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Scientific Opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize Bt11

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Abstract: Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) compiled its previous risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize Bt11, and considered their validity in the light of new relevant scientific publications published from 2005 onwards. Following a search of the scientific literature published between 2005 and October 2012, the EFSA GMO Panel identified 287 peer-reviewed publications containing evidence specific to the risk assessment and/or management of maize Bt11, of which 270 publications were previously discussed and cited in relevant GM maize-related applications and/or the numerous EFSA GMO Panel scientific outputs. From the remaining 17 publications, three were relevant for the food and feed safety assessment, and 14 for the environmental risk assessment and/or risk management of maize Bt11. None of these publications reported new information that would invalidate the previous conclusions on the safety of maize Bt11 made by the EFSA GMO Panel. Therefore, the EFSA GMO Panel considers that its previous risk assessment conclusions on maize Bt11, as well as its previous recommendations on risk mitigation measures and monitoring, remain valid and applicable.

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SCIENTIFIC OPINION

Scientific Opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize Bt11¹

EFSA Panel on Genetically Modified Organisms (GMOs)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) compiled its previous risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize Bt11, and considered their validity in the light of new relevant scientific publications published from 2005 onwards. Following a search of the scientific literature published between 2005 and October 2012, the EFSA GMO Panel identified 287 peer-reviewed publications containing evidence specific to the risk assessment and/or management of maize Bt11, of which 270 publications were previously discussed and cited in relevant GM maize-related applications and/or the numerous EFSA GMO Panel scientific outputs. From the remaining 17 publications, three were relevant for the food and feed safety assessment, and 14 for the environmental risk assessment and/or risk management of maize Bt11. None of these publications reported new information that would invalidate the previous conclusions on the safety of maize Bt11 made by the EFSA GMO Panel. Therefore, the EFSA GMO Panel considers that its previous risk assessment conclusions on maize Bt11, as well as its previous recommendations on risk mitigation measures and monitoring, remain valid and applicable.

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KEY WORDS

GMO, maize (*Zea mays*), Bt11, insect resistance, Cry1Ab, risk assessment, food and feed safety, environment, food and feed uses, import and processing, cultivation

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SUMMARY

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) compiled its previous risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize Bt11, and considered their validity in the light of new relevant scientific publications published from 2005 onwards.

The EFSA GMO Panel performed a search of the scientific literature to identify new scientific publications specific to maize Bt11 that may report new information relevant for the risk assessment and/or management of maize Bt11. Subsequently, the EFSA GMO Panel evaluated whether the information reported in recent publications, identified by the literature search, would invalidate its previous risk assessment conclusions on maize Bt11, as well as its previous recommendations on risk mitigation measures and monitoring.

Following a search of the scientific literature published between 2005 and October 2012, the EFSA GMO Panel identified 287 peer-reviewed publications containing evidence specific to the risk assessment and/or management of maize Bt11, of which 270 publications were previously discussed and cited in relevant GM maize-related applications and/or the numerous EFSA GMO Panel scientific outputs. From the remaining 17 publications, three were relevant for the food and feed safety assessment, and 14 for the environmental risk assessment and/or risk management of maize Bt11.

The EFSA GMO Panel did not identify peer-reviewed scientific publications reporting new information that would invalidate its previous conclusions on the safety of maize Bt11. Therefore, the EFSA GMO Panel considers that its previous risk assessment conclusions on maize Bt11, as well as its previous recommendations for risk mitigation measures and monitoring, remain valid and applicable.

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BACKGROUND AS PROVIDED BY EFSA

On 20 April 2005, the Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) issued a Scientific Opinion on the notification (reference C/F/96/05.10) for the placing on the market of the genetically modified (GM) insect resistant maize Bt11 for import and processing for feed uses, including cultivation, under Part C of Directive 2001/18/EC (EFSA, 2005). In EFSA (2005), the EFSA GMO Panel concluded that there was no evidence indicating that placing maize Bt11 on the market is likely to cause adverse effects on human or animal health or the environment in the context of its proposed uses. At the time, the EFSA GMO Panel also recommended that maize Bt11 cultivation should be accompanied by appropriate risk management strategies to delay the potential evolution of resistance to the Cry1Ab protein in target insects and to minimise exposure of non-target Lepidoptera (EFSA, 2005).

In both 2006 and 2008, the European Commission requested the EFSA GMO Panel to consider whether new evidence published in the scientific literature required a revision of the conclusions of its 2005 Scientific Opinion on maize Bt11 (EFSA, 2005). Following these requests, the EFSA GMO Panel evaluated the available new scientific information, and found no new evidence for adverse effects caused by the cultivation of maize Bt11 (EFSA, 2006, 2008). Therefore, the EFSA GMO Panel concluded that no new scientific information had been made available that would invalidate its previous risk assessment conclusions.

In 2009, the EFSA GMO Panel delivered a Scientific Opinion for the continued marketing of existing products produced from maize Bt11 for import, processing for food & feed uses, but not for cultivation (EFSA, 2009a). The EFSA GMO Panel concluded that: “*genetically modified maize Bt11 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses*”.

On 8 December 2010, the European Commission requested the EFSA GMO Panel to consider whether new scientific elements might require a revision of the conclusions of its previous Scientific Opinion on maize Bt11 in particular in the light of the mathematical model applied to the risk assessment of the insect resistant maize 1507.

On 30 November 2011, the EFSA GMO Panel adopted a Statement supplementing the environmental risk assessment conclusions and risk management recommendations on maize Bt11 cultivation. In its Statement, the EFSA GMO Panel concluded that: “*subject to appropriate management measures, maize Bt11 cultivation is unlikely to raise additional safety concerns for the environment compared to conventional maize*” (EFSA, 2011a).

Recently, the EFSA GMO Panel further supplemented its previous risk management recommendations on maize Bt11 for cultivation by reapplying the mathematical model developed by Perry et al. (2010, 2011, 2012), in order to consider additional hypothetical agricultural conditions, and to provide additional information on the factors affecting the insect resistance management plan (EFSA, 2012a).

On 20 June 2012, the EFSA GMO Panel was requested by the European Commission to deliver a Scientific Opinion updating the risk assessment and/or management of maize Bt11 in the light of recent scientific publications.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The European Commission requested EFSA: “*to adopt an opinion gathering its previously adopted conclusions on maize Bt11 for each area of risk and taking into account recent relevant scientific publications, in accordance with Article 29 of Regulation (EC) No 178/2002*”.

ASSESSMENT

1. INTRODUCTION

Maize Bt11 has been developed to provide protection against certain lepidopteran target pests, such as the European corn borer (ECB, *Ostrinia nubilalis*), and species belonging to the genus *Sesamia* (in particular the Mediterranean corn borer (MCB, *Sesamia nonagrioides*)), by the introduction of a part of a *Bacillus thuringiensis* (*Bt*) gene encoding the insecticidal Cry1Ab protein. The mode of action of the Cry1Ab protein and other Cry proteins is to bind selectively to specific receptors on the epithelial surface of the midgut of larvae of susceptible insect species, leading to death of larvae through pore formation, cell burst and subsequently septicaemia. Maize Bt11 also expresses the phosphinothricin-N-acetyltransferase (PAT) protein from *Streptomyces viridochromogenes*, which confers tolerance to the herbicidal active substance glufosinate-ammonium. The PAT protein expressed in maize Bt11 has been used as selectable marker to facilitate the selection process of transformed plant cells, and is not intended for weed management purposes.

This EFSA GMO Panel Scientific Opinion addresses all intended uses of maize Bt11, covering the import, processing, and food and feed uses, as well as cultivation. Since the scope of the notification C/F/96/05.10 did not cover the use of glufosinate-ammonium-based herbicides on maize Bt11, potential effects due to the use of such herbicides on maize Bt11 are not considered in this Scientific Opinion.

In accordance with the terms of reference laid down by the European Commission, this Scientific Opinion is based on existing scientific outputs on maize Bt11 by the EFSA GMO Panel (i.e., EFSA, 2005, 2006, 2008, 2009a,e), focusing in particular on the most recent ones (e.g., EFSA, 2010c,d, 2011a,e, 2012a,d). To comply with the current mandate of the European Commission, the EFSA GMO Panel performed a search of the scientific literature to identify new scientific publications specific to maize Bt11 that may report new information relevant for the risk assessment and/or management of maize Bt11 (EFSA, 2010a). The EFSA GMO Panel scrutinised the new scientific publications identified during the literature search, and subsequently assessed whether the information reported in these publications would invalidate its previous conclusions on the safety of maize Bt11.

2. LITERATURE SEARCH

In response to the present request of the European Commission and in addition to the continuous screening of relevant scientific literature by the EFSA GMO Panel, an additional search of the scientific literature was performed. The aim of this search was to identify new scientific publications specific to maize Bt11 that may report new information relevant to the risk assessment and management of maize Bt11.

The scientific literature database ISI Web of Knowledge⁴ (Thompson Reuters, New York, USA) was used for the literature search. Literature was searched and filtered in a stepwise manner. As a first step, the following combination of generic keywords being both event- and trait-specific was used to retrieve all references for further consideration: “TOPIC FIELD = *Bt11* OR *Bt_11* OR *Cry*1Ab* AND *maize*”. The search by keywords using the topic field enabled the retrieval of publications that contain these keywords, either in the publication’s title, list of keywords, or abstract. The asterisk (wildcards) was used to cover all the possible written forms of the keyword Cry1Ab (e.g., Cry1Ab, Cry 1Ab, Cry_1Ab). In the second step, search results were sorted by the area of scientific discipline (e.g., molecular characterisation, comparative analysis, food and feed safety assessment, environmental risk assessment (ERA) and post-market environmental monitoring (PMEM)) and subsequently considered by the EFSA GMO Panel (see sections below). The search for scientific publications targeted publications published between 2005 – the year during which the EFSA GMO Panel issued its first Scientific Opinion on maize Bt11 for all uses, including cultivation (see EFSA, 2005) – and October 2012. The EFSA GMO Panel also performed targeted searches of relevant peer-reviewed

⁴ This database includes: Web of Science, CABI, FSTA, MedLine and Current Contents Connect databases

journals, in order to identify the most recent publications appearing ahead of print, and which may not have been included in the ISI Web of Knowledge yet.

Publications on the coexistence of maize cropping systems, the detection, quantification, labelling and traceability of GMOs, socio-economics and public perception were excluded, as these topics are not in the remit of the EFSA GMO Panel. In case of lack of clarity on the GM event used for the study, the publication at stake was not considered of relevance for the current mandate. After having accounted for the scientific literature previously discussed and cited in relevant GM maize-related applications⁵ and/or the numerous EFSA GMO Panel scientific outputs (EFSA, 2005, 2006, 2008, 2009a,b,c,d,e, 2010c,d, 2011a,b,c,d,e, 2012a,b,c,d,e), the EFSA GMO Panel found 17 relevant peer-reviewed publications written in English that it had not previously discussed (see sections below; Appendix A – rows highlighted in grey). Taking into account similarities between both Cry1Ab-expressing maize transformation events Bt11 and MON 810 (e.g., identity of amino acid sequence of the core protein, similar biological activity against sensitive Lepidoptera, similar Cry1Ab protein expression level in pollen) (EFSA, 2011a), the EFSA GMO Panel considered it relevant to screen also MON 810-related publications for a comprehensive risk assessment of maize Bt11 (EFSA, 2012d).

The EFSA GMO Panel identified a total number of 287 peer-reviewed publications containing evidence specific to the risk assessment and/or management of maize Bt11, of which 270 publications were previously discussed and cited in relevant GM maize-related applications and/or the numerous EFSA GMO Panel scientific outputs. From the remaining 17 publications, three were relevant for the food and feed safety assessment of maize Bt11, and 14 for the environmental risk assessment and/or risk management of maize Bt11.

Even though no systematic review of the literature is carried out in this Scientific Opinion, the EFSA GMO Panel adhered to some fundamental principles of systematic review, which can be summarised as follows: methodological rigour and coherence in the retrieval and selection of publications; transparency; and reproducibility of the performed literature search (EFSA, 2010a).

3. MOLECULAR CHARACTERISATION

3.1. Introduction

The summary of the previous assessments of maize Bt11, presented below, covers the following key areas of molecular characterisation: (1) description of the methods used for the genetic modification; (2) source and characterisation of nucleic acid used for transformation; (3) description of the traits and characteristics which have been introduced; (4) information on the sequences actually inserted; (5) information on the expression of the inserted sequence; and (6) genetic stability of the inserted sequence and phenotypic stability of the GM plant.

3.2. Summary of previous conclusions by the EFSA GMO Panel

Maize Bt11 was developed by electroporation of and regeneration from maize protoplasts. As a result of the genetic modification, the maize Bt11 transformation event contains an insert bearing both a variant *cry1Ab* gene from *Bacillus thuringiensis* (driven by a 35S *Cauliflower mosaic virus* promoter (P35S)) to confer resistance to certain lepidopteran target pests and a *pat* gene from *Streptomyces viridochromogenes* (driven by a P35S), as a selectable marker providing tolerance to glufosinate-ammonium-based herbicides.

Molecular analysis showed that maize Bt11 contains a single copy of the insert in the nuclear genome of the GM plant. The structure of the insert in maize Bt11 was determined by Southern analyses and DNA sequencing. Updated bioinformatic analysis supports the conclusion that the genomic sequences in both 5' and 3' regions flanking the insert of maize Bt11 transformation event show similarity to

⁵ GM plant market registration dossier with reference EFSA-GMO-RX-MON 810, EFSA-GMO-RX-Bt11, C/F/96/05.10 and EFSA-GMO-BE-2010-79

highly repetitive *knob*-associated sequences. Analysis of the open reading frames (ORFs) spanning the junction identified no putative peptides showing significant similarities to known toxins or allergens.

The Cry1Ab and PAT proteins in field grown plants were expressed in all tissues examined (i.e., leaf, pollen, silk, stalk, root, whole plant and grain), with concentrations decreasing at the time of plant maturation and senescence. The level of Cry1Ab protein was similar in leaf, husk and stalk (ranging between 20 and 168 µg/g total protein) and was significantly lower in kernels (ranging between 0.4 and 8.2 µg/g total protein). Quantifiable levels of the PAT protein were found only in leaves, silk and tassel. For kernels, pollen, root and stalk concentrations were below the limits of detection.

The genetic stability of the inserted DNA in maize Bt11 transformation event was demonstrated over multiple generations and segregation data for PAT and Cry1Ab were shown to follow Mendelian genetics.

All previous assessments of maize Bt11 by the EFSA GMO Panel (EFSA, 2005, 2009a) concluded that the molecular characterisation of maize Bt11 does not raise a safety issue.

3.3. Results from the literature search

From the literature search, no new peer-reviewed scientific publications related to the molecular characterisation of maize Bt11 were identified.

3.4. Conclusion

In the absence of new scientific evidence specific to the molecular characterisation of maize Bt11, the EFSA GMO Panel considers that its previous conclusions on the molecular characterisation of maize Bt11 remain valid and applicable.

4. COMPARATIVE ANALYSIS

4.1. Introduction

The summary of the previous assessments of maize Bt11, presented below, covers the following key areas of the comparative analysis: (1) choice of comparator and production of material for the compositional assessment; (2) compositional analysis; and (3) agronomic traits and GM phenotype.

4.2. Summary of previous conclusions by the EFSA GMO Panel

Maize Bt11 was compared with isogenic non-GM comparators. Forage and grain were collected for compositional analysis from field trials conducted in the US (studies involving 3-6 sites in 1995) and France (two locations in 1998). Based on the results of the compositional analysis, the EFSA GMO Panel concluded that forage and grain of maize Bt11 were compositionally equivalent to those of conventional maize, except for the presence of the proteins Cry1Ab and PAT in maize Bt11. In addition, field trials over several seasons and at different locations in the EU (Spain, France, Italy and Portugal between 1994 and 2003) did not reveal unexpected changes of agronomic characteristics and performance (EFSA, 2005).

The same field trials were used in the evaluation of the renewal application for the continued marketing of existing products produced from maize Bt11 in 2009 (EFSA-GMO-RX-Bt11), and in three applications for market introduction of insect resistant and herbicide tolerant stacked GM maize Bt11 x GA21 (EFSA-GMO-UK-2007-49), Bt11 x MIR604 (EFSA-GMO-UK-2007-50) and Bt11 x GA21 x MIR604 (EFSA-GMO-UK-2008-56) for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (EC, 2003). The EFSA GMO Panel concluded that: *"no new information has appeared since 2005 which would indicate differences in the composition of products derived from maize Bt11, as compared to its non-GM maize counterpart"* (EFSA, 2009a,e, 2010c,d).

4.3. Results from the literature search

A thorough literature search did not identify any new scientific publication dealing with the compositional or agronomic characteristics of maize Bt11.

4.4. Conclusion

In the absence of new scientific evidence specific to maize Bt11, previous EFSA GMO Panel conclusions on maize Bt11 remain valid and applicable.

5. FOOD AND FEED SAFETY ASSESSMENT

5.1. Introduction

The summary of the previous assessments of maize Bt11, presented below, covers the following key areas of the food and feed safety assessment: (1) product description and intended use; (2) effect of processing; (3) toxicology; (4) allergenicity; (5) nutritional assessment of GM food and feed; and (6) post-market monitoring of GM food and feed.

5.2. Summary of previous conclusions by the EFSA GMO Panel

Bioinformatics-supported studies showed that the amino acid sequences of the newly expressed Cry1Ab and PAT proteins do not show any significant similarity with known toxins or allergens. For safety testing, the respective proteins produced in recombinant *Escherichia coli* strains were used after it had been demonstrated that these proteins were equivalent to those produced in maize Bt11. The microbially produced Cry1Ab and PAT proteins were rapidly degraded in simulated gastric fluid. The Cry1Ab protein did not induce adverse effects in an acute oral toxicity study in mice. There were no indications of adverse effects after repeated-dose oral administration of the PAT protein to rats. With regard to the whole product, feeding studies with maize Bt11 using different target animals, such as broiler chickens and laying hens fed grains, as well as dairy cows and beef cattle (steers) fed silage, indicated that maize Bt11 is nutritionally equivalent to the respective non-GM control (EFSA, 2005).

In the evaluation of the renewal application (EFSA-GMO-RX-Bt11), information from an updated literature review and additional studies did not lead the EFSA GMO Panel to change its previous opinion that maize Bt11 is as safe and nutritious as the non-GM counterparts (EFSA, 2009a). The EFSA GMO Panel confirmed this view in response to three applications for the market introduction of insect resistant and herbicide tolerant stacked GM maize Bt11 x GA21 (EFSA-GMO-UK-2007-49), Bt11 x MIR604 (EFSA-GMO-UK-2007-50) and Bt11 x GA21 x MIR604 (EFSA-GMO-UK-2008-56) for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (EFSA, 2009e, 2010c,d).

5.3. Results from the literature search

5.3.1. Safety assessment of maize Bt11

From the literature search, the following three new peer-reviewed scientific publications containing evidence specific to maize Bt11 for this specific area of risk were identified and scrutinised for their possible relevance with respect to the food and feed safety of maize Bt11:

- Nakajima et al. (2007) characterised the IgE antibodies of human sera by enzyme-linked immunosorbent assay (ELISA) and immunoblotting. For the ELISA assay, a soluble form of the Cry1Ab protein, purified from *E. coli* transformed with a DNA sequence from maize Bt11, was used as antigen. All tested sera from patients allergic to major food allergens did not contain IgE antibodies directed against Cry1Ab.
- Nakasuji et al. (2008) monitored the presence of common enterobacterial genes, a ubiquitous plant chloroplast gene, maize intrinsic zein (*Ze1*) and recombinant *cry1Ab* gene in the gastrointestinal contents, peripheral blood mononuclear cells and visceral organs of mice and their progeny fed

with maize Bt11. The enterobacterial and chloroplast genes were detected inconsistently in peripheral blood mononuclear cells, visceral organs, milk or liver of suckling mice, while *Ze1* and *cry1Ab* were not detected. These results suggest that feed-derived enterobacterial and plant DNAs were incompletely degraded in the gastrointestinal tract, and part of them were absorbed into organs or milk as a source of transfer into suckling mice, but the *cry1Ab* gene was not transferred.

- Haryu et al. (2009) carried out a reproduction toxicity study over five generations in mice fed diets containing 68 % maize Bt11 or its non-GM isoline. Parent generation (F0) consisted of 31 females and 16 males. They were cross-bred at the age of 60-70 days. The rate of vaginal plug formation, delivery rate and period, number of fetuses, sex ratio of fetuses, weaning period and feed intake and individual body weight were recorded. F1 mice were bred in the same manner to generate the follow-up generations. One day before delivery of F4 fetuses, the pregnant mice were sacrificed to count the number of fetuses, determine possible abnormalities as well as size and weight of placenta and ovaries. There was no relevant difference in growth, reproduction performance and life span between the GM and control groups.

5.3.2. Nutritional assessment of maize Bt11

A thorough literature search did not identify any new scientific publication dealing with the nutritional assessment of maize Bt11.

5.3.3. Safety of maize Bt11 pollen occurring in or as food

With regard to the safety of pollen from maize Bt11, the EFSA GMO Panel refers to the Statement on the safety of maize MON 810 pollen occurring in or as food (EFSA, 2011e). The same rationale used in that Statement is applicable to evaluate the safety of maize Bt11 pollen occurring in or as food. Therefore, while the EFSA GMO Panel is not in a position to conclude on the safety of maize pollen in or as food in general, it concludes that the genetic modification in maize Bt11 does not constitute an additional health risk if maize Bt11 pollen were to replace that of non-GM maize in or as food.

5.4. Conclusion

The newly identified publications are consistent with and support the previous risk assessments made by the EFSA GMO Panel (EFSA, 2005, 2009a,e, 2010c,d). As a consequence, the previous EFSA GMO Panel conclusions on maize Bt11 remain valid and applicable.

6. ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STRATEGIES

6.1. Environmental risk assessment

The outline of this EFSA GMO Panel Scientific Opinion follows the key areas of environmental risk as defined in Directive 2001/18/EC and EFSA (2010b): (1) changes in plant fitness due to the genetic modification; (2) potential for gene transfer and its environmental consequences; (3) interactions between the GM plant and target organisms; (4) interactions between the GM plant and non-target organisms (NTO); (5) effects on animal and human health; (6) interactions with biogeochemical processes and the abiotic environment; (7) impacts of the specific cultivation, management and harvesting techniques; and (8) risk management strategies (including PMEM).

The EFSA GMO Panel previously concluded that: “the cultivation of maize Bt11 could have the following adverse effects on the environment in the context of its intended uses: (1) the adoption of altered pest control practices with higher environmental load due to potential evolution of resistance to the Cry1Ab protein in populations of exposed lepidopteran target pests; and (2) reductions in populations of certain ‘extremely sensitive’ non-target lepidopteran species where high proportions of their populations are exposed over successive years to high levels of maize Bt11 pollen deposited on their host-plants” (EFSA, 2011a).

6.1.1. Changes in plant fitness due to the genetic modification

The EFSA GMO Panel previously evaluated the altered potential of maize Bt11 in terms of fitness, persistence and invasiveness (EFSA, 2005).

6.1.1.1. Summary of previous conclusions by the EFSA GMO Panel

The EFSA GMO Panel indicated that: “*there are no indications for an altered ecological fitness of the GM maize in comparison to conventionally bred hybrids with similar genetic background*” (EFSA, 2005).

6.1.1.2. Results from the literature search

From the literature search, no new peer-reviewed scientific publications containing evidence specific to maize Bt11 for this specific area of risk were identified.

6.1.1.3. Conclusion

In the absence of new scientific evidence specific to maize Bt11 for this specific area of risk, the EFSA GMO Panel considers that its previous conclusions on changes in plant fitness due to the genetic modification remain valid and applicable.

6.1.2. Potential for gene transfer

The EFSA GMO Panel previously evaluated the potential for horizontal and vertical gene flow of maize Bt11, as well as the potential environmental consequences of such gene transfer (EFSA, 2005).

6.1.2.1. Summary of previous conclusions by the EFSA GMO Panel

Concerning the potential for horizontal gene transfer, the EFSA GMO Panel indicated that: “*taking into account the origin and nature of these genes and the lack of selective pressure in the intestinal tract and/or the environment, the likelihood that horizontal gene transfer would confer selective advantages or increased fitness on microorganisms is very limited. For this reason it is very unlikely that genes from Bt11 maize would become established in the genome of microorganisms in the environment or human and animal digestive tract. In the very unlikely event that such a horizontal gene transfer would take place, no adverse effects on human and animal health and the environment are expected as no principally new traits would be introduced into microbial communities*” (EFSA, 2005).

Regarding a possible plant-to-plant gene transfer, the EFSA GMO Panel indicated that: “*Bt11 maize has no altered survival, multiplication or dissemination characteristics except in the presence of glufosinate ammonium*” and that: “*the likelihood of unintended environmental effects due to the establishment and spread of maize Bt11 will be no different to that of traditionally bred maize*”. As for any other maize cultivars, it was considered very unlikely that volunteers could survive until subsequent seasons or would establish undesirable populations under European environmental conditions (EFSA, 2005).

6.1.2.2. Results from the literature search

From the literature search, the following new peer-reviewed scientific publication containing evidence specific to maize Bt11 for this specific area of risk was identified and scrutinised for its possible relevance for the ERA of maize Bt11:

- Tremblay et al. (2008) investigated the fate of the Cry1Ab protein and of its coding sequence in forage and rumen digesta from cows fed maize Bt11 to evaluate the persistence of the recombinant DNA as a possible substrate for horizontal gene transfer to rumen microorganisms and the potential for the Cry1Ab protein release into the environment. The experimental design, a complete randomised block with four replicates, included two maize Bt11 hybrids and the appropriate isolines. Seven mini-silos were made and were opened at different time points, 0, 1, 2, 4, 8, 16, 32

and 64 days after ensiling. The residual maize forage from each hybrid was used to ensile in plastic bag (containing 500 kg of maize forage) and sampled at 30 and 198 days after ensiling. To complete the trial, two cows per maize hybrid were fed *Bt*-maize silage over seven days. Samples of 'ruminal forage digesta' and 'rumen fluid' were collected at four different time-points. The authors used PCR to detect recombinant DNA and ELISA to quantify the Cry1Ab protein. The authors concluded that the integrity of recombinant DNA and its ability to encode functional proteins are rapidly lost during the ensiling process. However, they observed that a certain proportion of the *cry1Ab* gene can persist during silage conservation, and that the Bt protein is rapidly but not completely degraded during silage fermentation. After seven days' feeding with *Bt*-maize silage, the Cry1Ab protein was detected in very low concentration in the ruminal forage digesta, but was undetectable in rumen fluid. The study confirms that Bt proteins and their encoding genes are degraded during ensiling, grain processing and passage through the ruminant forestomach. The authors concluded that the transfer of recombinant DNA to rumen microorganisms and the possible adverse effects of the Cry1Ab protein on NTOs are highly unlikely.

6.1.2.3. Conclusion

Results reported by Tremblay et al. (2008) do not provide new information that would invalidate the previous conclusions on potential gene transfer from maize Bt11 and its potential environmental consequences made by the EFSA GMO Panel. Therefore, the EFSA GMO Panel considers that its previous conclusions on maize Bt11 remain valid and applicable.

6.1.3. Interactions of the GM plant with target organisms

The potential for maize Bt11 to cause adverse effects through direct or indirect interactions between the GM plant and target organisms was previously evaluated by the EFSA GMO Panel (EFSA, 2005, 2006, 2008), and the outcome of these evaluations has been updated recently in the light of new relevant scientific publications (EFSA, 2011a, 2012a).

6.1.3.1. Summary of previous conclusions by the EFSA GMO Panel

The EFSA GMO Panel considered that: *"the possible evolution of resistance to the Cry1Ab protein in lepidopteran target pests as a relevant environmental and agronomic concern associated with the cultivation of maize Bt11, as the consequences of resistance evolution may lead to altered pest control practices that may cause adverse environmental effects"* (EFSA, 2011a).

6.1.3.2. Results from the literature search

From the literature search, the following seven new peer-reviewed scientific publications containing evidence specific to maize Bt11 for this specific area of risk were identified and scrutinised for their possible relevance for the ERA of maize Bt11:

- Allen and Pitre (2005) performed preliminary tests to compare the toxicity of two maize MON 810 events on southwestern corn borer (SCB, *Diatraea grandiosella*). The GM events and their conventional counterparts used as controls were planted in a complete randomised block design and no insecticides were applied. Plant material was sampled at different phenological phases from different tissues and lyophilised. SCB larvae were fed a mixture containing different concentrations of plant material (15,000; 1,500; 150 and 15 µg/ml of diet) from specific tissue sampled at different plant stages for six days. Larval survival and body weight were measured seven days after and the value of 1,500 µg of lyophilised *Bt*-tissue per ml of diet was chosen as discriminatory dose used in subsequent evaluations. The authors identified considerable variability in response of SCB larval survival and body weight to different plant tissue from GM and control maize. As the concentration of Bt toxin in the artificial diet increased, SCB larval survival, body length and weight decreased. The authors concluded that further investigation is needed in order to evaluate the effects that the plant material may have on target pests and subsequently to assess the efficacy of the high dose/refuge strategy (see Section 6.2).

- Chilcutt et al. (2007) investigated the efficacy of hybrid maize events MON 810, Bt11 and Bt176 against the target pests, corn earworm (CEW, *Helicoverpa zea*) and fall armyworm (FAW, *Spodoptera frugiperda*), under field conditions during two years (2001 and 2002) in the USA. *Bt*- and non-*Bt*-maize were planted in a randomised complete block with nine blocks at each site. During ear formation, instar densities of CEW and FAW were recorded for each *Bt*-maize event. Densities of 1st, 2nd, and 5th CEW instars were each affected by maize MON 810 and Bt11, but not by maize Bt176. First and 2nd CEW instars were found in higher numbers on ears of maize MON 810 and Bt11 than on non-*Bt*-maize. Densities of 3rd and 4th instars were equal on *Bt*- and non-*Bt*-maize, whereas densities of 5th instars were lower on *Bt*-maize. FAW larval densities were affected only during one year when 2nd, and 4th to 6th instars were lower on ears of maize MON 810 and Bt11, compared with their non-*Bt*-maize. In conclusion, the authors found that densities for 2nd, and 4th to 6th FAW instars and for 5th CEW instars were lower on ears of *Bt*-maize than non-*Bt*-maize, with 1st and 2nd CEW instars occurring in higher numbers on *Bt*-maize ears. The authors concluded that these results are probably due to a combination of Bt toxins slowing development of early instars, when cannibalism is low, before eventually killing them.
- Nuessly et al. (2007) carried out three-year field trials using a randomised complete block design to measure resistance of FAW and *Euxesta stigmatias*, a sweet corn pest, to Lepidoptera-resistant corn varieties derived from both, endogenous (i.e., maysin-expressing sweet corn varieties) and exogenous sources (i.e., Cry1Ab-expressing sweet corn varieties Bt11). An additional field experiment assessed resistance to both pests jointly by using a split-plot experiment arranged in a randomised complete block design. In all experiments, damage to sweet corn ears caused by each insect was rated on different scales. Both endogenous and exogenous-resistant varieties showed equivalent control against FAW, whereas they are susceptible to *E. stigmatias* infestations, in spite of the known cross-activity of Cry1Ab proteins to Diptera (van Frankenhuyzen K., 2009). The authors concluded that the results provide further evidence that insect resistant traits associated with exogenous and endogenous genes can provide effective control of key target insect pests in agricultural systems. The authors also demonstrated that interactions between pest species can affect the efficacy of different exogenous and endogenous pest resistance traits.
- Dalmacio et al. (2007) studied the efficacy of Cry1Ab-expressing maize to control the Asian corn borer (ACB, *Ostrinia furnicalis*) and in particular to reduce the incidence of the bacterial stalk and ear rot often caused by ACB in the Southeast Asia. ACB is a pest that is not present in Europe (Meissle et al., 2012). In the field, three Cry1Ab-expressing maize hybrids and their isogenic lines were tested in seven locations in the Philippines over the 2003-2004 growing season. Yield, tunnelling by ACB and bacterial rot incidence were measured. Dalmacio et al. (2007) showed that *Bt*-maize was less or not affected by ACB, had a higher yield and was less affected by the bacterial disease than the control maize. The authors therefore considered that Cry1Ab-expressing maize appears to reduce the disease incidence associated with damage caused by ACB.
- Rasco et al. (2008) tested the efficacy of three maize Bt11 hybrids and of their isolines, including also two commercial non-*Bt* hybrids under greenhouse conditions and artificial ACB infestation. The plants were cultivated in pots following a complete randomised experimental design with 10 replicates. Plants were evaluated twice showing that the Bt11 hybrids expressing the Cry1Ab protein were highly resistant to ACB. *Bt*-maize plants presented little or no visible injuries to leaves and zero to minimal damages were identified on stalks, ear shanks, ears, tassels and kernels. Even though the Cry1Ab protein levels were not quantified in the test material and the effects of background resistance genes unknown, the results confirm the efficacy of the tested *Bt*-maize hybrids expressing the Cry1Ab protein against the tested population of ACB.
- Hari et al. (2008) assessed the efficacy of several maize MON 810 hybrids against the spotted stem borer (SSB, *Chilo partellus*) under laboratory and field conditions. That species is an important target lepidopteran maize pest in India, and neonates initially feed on maize by scraping the leaf lamina before migrating to bore into the stem. In the field in India, the experimental set-up foresaw two replicates per treatment in a randomised block design; leaf damage was reported for GM and

control plants as an indicator of the effectiveness of GM maize against neonate and 15-day old SSB larvae. The authors reported a higher percentage damage of control maize. In parallel, in the laboratory, SSB larvae were exposed to GM and control maize leaf discs; the study design included 5 replicates per treatment in a completely randomised design. Leaf consumption and larval mortality were measured. The authors indicated that neonate larvae consumed less GM maize leaf material and showed a 100 % mortality rate when feeding on GM maize. Even though the Cry1Ab protein levels were not quantified in the test material, the protein content in the tested genetic backgrounds appeared to be sufficient to affect the SSB larvae. Based on the results, the authors concluded that the maize MON 810 hybrids tested may be suitable to control SSB in India.

- Burkness et al. (2010) compared the efficacy of pyramided⁶ *Bt*-maize expressing both the Vip3A and Cry1Ab protein and the single *Bt*-maize events MIR162 (Vip3A) and Bt11 (Cry1Ab) against the target pests, CEW, ECB and FAW, under field conditions in the USA (over four growing seasons in Maryland and two growing seasons in Minnesota). Plots were arranged in a randomised complete block design with four replications and managed according to standard sweet corn growing practices, including overhead or drip irrigation, and no insecticides were applied. Non-*Bt*-maize with similar genetic background was included in all experiments and also planted as a buffer between plots and around the perimeter of the study sites. Over all years and locations, non-*Bt*-maize, without insecticide protection averaged between 43 and 100 % ears infested with a range of 0.24 to 1.74 CEW larvae per ear. In the pyramided *Bt*-maize, no larvae of the considered pest species were found and only minimal kernel damage (probably due to other insect pests) was recorded. Maize Bt11 incurred a moderate level of CEW feeding damage, with surviving larvae mostly limited to the 1st or 2nd instar, probably as a result of previously documented growth inhibition from Cry1Ab. The combined data for both Maryland and Minnesota from 2007 to 2010 indicated that both the pyramided *Bt*-maize and maize Bt11 provided high levels of control against ECB larvae. The highest levels of control against FAW were observed for the pyramided *Bt*-maize and maize MIR162. Based on these results, the authors concluded that pyramiding of the Vip3A and Cry1Ab proteins appears to provide an improved means of managing major lepidopteran target pests of maize in two regions of USA, by providing a high dose when expressed in combination.

6.1.3.3. Conclusion

From the literature search, only the paper by Burkness et al. (2010) studied an European maize pest (ECB) and confirmed the high level of control of maize Bt11 against ECB. The other aforementioned papers studied species which do not occur in Europe (Meissle et al., 2012) and indicated that most of them, except CEW and FAW, may be effectively controlled by maize Bt11. In this respect, the EFSA GMO Panel recommends caution when predicting future responses of ECB and MCB in relevant EU regions based on experiences elsewhere or with other target insect pest species, as resistance evolution is dependent upon many factors. Furthermore, caution must be exercised when extrapolating laboratory and greenhouse results with artificially selected resistant strains to field conditions.

Results reported by Chilcutt et al. (2007), Nuessly et al. (2007), Dalmacio et al. (2007), Rasco et al. (2008), Hari et al. (2008) and Burkness et al. (2010) do not provide new information that would invalidate the previous conclusions on interaction of maize Bt11 with target organisms made by the EFSA GMO Panel. Therefore, the EFSA GMO Panel considers that its previous conclusions on maize Bt11 remain valid and applicable.

6.1.4. Interactions of the GM plant with non-target organisms

The potential of maize Bt11 to have direct or indirect adverse effects on NTO and the ecosystem services they provide in agro-ecosystems was previously evaluated by the EFSA GMO Panel (EFSA, 2005, 2006, 2008, 2011a) and the outcome of these evaluations has been recently updated in the light of new relevant scientific publications (EFSA, 2011a, 2012a).

⁶ A pyramided *Bt*-crop combines related traits such as insect resistance against target insect pest species of the same Order.

6.1.4.1. Summary of previous conclusions by the EFSA GMO Panel

In 2005, the EFSA GMO Panel indicated that: “*on the basis of the available data delivered either by the applicant or by literature survey, the likelihood of adverse effects on non-target organisms or on soil function is foreseen to be very low*” (EFSA, 2005). In 2006 and 2008, the EFSA GMO Panel confirmed its previous conclusions on the environmental safety of maize Bt11, including on the potential impact of the Cry proteins on NTOs (EFSA, 2006, 2008). The EFSA GMO Panel concluded that: “*Bt11 and 1507 maize are unlikely to have adverse effects on human and animal health or the environment in the context of their proposed uses*” (EFSA, 2006).

Using a mathematical model of exposure to assess potential adverse effects resulting from exposure of non-target lepidopteran species to Cry1Ab-containing maize pollen deposited on their host-plants under representative cultivation conditions (Perry, 2011a,b; Perry et al., 2010, 2011, 2012, cited in EFSA, 2011a), the EFSA GMO Panel concluded that: “*that there is a risk to certain ‘extremely sensitive’ sensitive non-target lepidopteran species⁷ where high proportions of their populations are exposed over successive years to high levels of maize Bt11 (and/or maize MON 810) pollen deposited on their host-plants*” (EFSA, 2011a, 2012a).

6.1.4.2. Results from the literature search

From the literature search, the following three new peer-reviewed scientific publications containing evidence specific to maize Bt11 for this specific area of risk were identified and scrutinised for their possible relevance for the ERA of maize Bt11:

- Turlings et al. (2005) compared the odour emissions of leaves of maize Bt11 and its near-isogenic line following scratching with a scalpel and application of *Spodoptera littoralis* regurgitant to the damaged sites, and tested the relative attractiveness of induced plant odours to the endoparasitoids *Cotesia marginiventris* and *Microplitis rufiventris*. Both wasps are braconids and attack early larval stages of various lepidopteran pests. The authors postulated that if maize Bt11 and its near-isogenic line differ in the odours they emit, this may be reflected in the responses of the wasps. Chemical analyses of collected odours revealed significant quantitative differences between maize Bt11 and its near-isogenic line, but they all fell in the range of variability observed for other maize genotypes. Both parasitoid species were strongly attracted to induced maize odour. Despite the differences between the odours of maize Bt11 and its near-isogenic line, neither wasp distinguished between the odours of both maize lines. In addition, wasps that had previously experienced one of the odours during a successful oviposition divided their choices equally between the two odours. The results indicate that the quantitative differences between the odours of maize Bt11 and its near-isogenic line had no measurable effect on the wasps’ behaviour.
- Li et al. (2005) studied the frequency of dispersal and deposition of Cry1Ab-expressing maize pollen (maize MON 810 event) nearby maize fields in order to investigate the possible risks of the GM pollen for the tussah silkworm, *Antheraea pernyi*, an important natural resource for the silk industry in China. The tussah silkworm is not present in Europe (Meissle et al., 2012). From the field experiment, the authors concluded that the pollen deposition on wild host-plants near maize fields rapidly declined with distance from the edge of the GM maize field. In addition, the laboratory experiment did not show significant differences in the larval mortality and weight of the silkworms between the GM and non-GM maize pollen treatment, apart from weights of 2nd and 3rd instars when exposed to pollen levels much higher than pollen levels on their host plants growing near maize fields. The authors concluded that the effects of Cry1Ab-expressing maize pollen on the Chinese silkworm are likely to be negligible under common field conditions.
- Harwood et al. (2006) studied the fate of the Cry1Ab protein in different gut compartments of the field slug, *Deroceras reticulatum*, after ingestion of maize Bt11 kernels. After a three hours

⁷ Here, an ‘extremely sensitive’ species means a species in the highest sensitivity category as defined in Table 2 of EFSA (2011b).

feeding period on Bt11 or control maize kernels, slugs were collected over an incremental period of time (from 2 up to 144 hours). Slugs samples were homogenised and the Cry1Ab decay rate was measured by ELISA. This approach demonstrated that Cry1Ab protein within slugs decayed at an exponential rate over time and that the Cry1Ab protein is still detected four days after the three hours feeding period. The concentration of Cry1Ab protein firstly declined from 2 to 0.5 ng/g fresh weight and afterwards below the detection level. There was no indication of accumulation of Cry1Ab protein in the gut, but the decay demonstrated its instability in slugs. Considering that the ingestion rate of Cry1Ab protein would be higher under field conditions and that slug predators may be exposed to Cry1Ab protein, the authors concluded that further investigation is needed under field conditions. In summary, the study demonstrated the uptake and degradation of Cry1Ab protein by field slugs and indicated that possible effects on non-target slug predators need to be considered.

6.1.4.3. Conclusion

Results reported by Turlings et al. (2005), Li et al. (2005) and Harwood et al. (2006) do not provide new information that would invalidate the previous conclusions on interactions of maize Bt11 with NTO made by the EFSA GMO Panel. Therefore, the EFSA GMO Panel considers that its previous conclusions on maize Bt11 remain valid and applicable.

6.1.5. *Effects on human and animal health*

The potential of maize Bt11 to have adverse effects on human and animal health was previously evaluated by the EFSA GMO Panel (EFSA, 2005, 2009a).

6.1.5.1. Summary of previous conclusions by the EFSA GMO Panel

The molecular analysis, comparative analysis and the food and feed safety assessment of maize Bt11 did not raise safety concerns for human and animal health. Therefore, in its previous Scientific Opinion on maize Bt11 (EFSA, 2009a), the EFSA GMO Panel concluded that: “*maize Bt11 is unlikely to have adverse effects on human and animal health or the environment in the context of its proposed use*”.

6.1.5.2. Results from the literature search

See sections 3, 4 and 5 for further details.

6.1.5.3. Conclusion

See sections 3, 4 and 5 for further details.

6.1.6. *Interactions with biogeochemical processes and the abiotic environment*

The EFSA GMO Panel previously considered the possible environmental exposure to the Cry1Ab protein introduced into the soil via physical damage to plant tissues, via decomposition of shed root cells during plant growth, via decomposing plant residues remaining in fields after harvest and that might be incorporated into the soil during tillage operations, and possibly via root exudates (EFSA, 2005).

6.1.6.1. Summary of previous conclusions by the EFSA GMO Panel

The EFSA GMO Panel indicated that: “*adverse effects due to slightly altered decomposition rates are unlikely*” and that: “*effects on biogeochemical processes resulting from pat expression and glufosinate ammonium treatment are likely to be the same as effects resulting from cultivation of non-GM maize*” (EFSA, 2005).

6.1.6.2. Results from the literature search

From the literature search, the following two new peer-reviewed scientific publications containing evidence specific to maize Bt11 for this specific area of risk were identified and scrutinised for their possible relevance for the ERA of maize Bt11:

- Margarit et al. (2008) investigated the levels of Cry1Ab protein rhizo-secreted by the GM maize Bt11, MON 810 and Bt176 events in hydroponic cultures. The amounts of Cry1Ab protein rhizo-secreted by different GM maize events grown under hydroponic conditions, after three weeks, were found to be 94 pg x plant (for maize MON 810), undetectable (for maize Bt176 and non-GM maize), and 19 pg x plant (for maize Bt11). The levels of Cry1Ab protein exudated correlate with the levels of Bt protein expression in root tissue. In addition, the study was extended to the presence and origin of Cry1Ab protein and *cry1Ab*-encoding genes (DNA) in soil cultivated with GM- and non-GM maize. The *cry1Ab* gene was identified and a basal level (30 pg/g of soil) of Cry1Ab protein was immunologically detected in soils of the control plots cultivated with non-GM maize (and where *Bt*-bioinsecticide was never sprayed), possibly of bacterial origin. Indeed, *Bacillus thuringiensis* could be isolated by cultivation from these soils, supporting the assumption of naturally produced Cry1Ab protein in soils. Furthermore, when soil DNA was analysed for the presence of *cry1Ab*-encoding genes, those could also be detected in non-*Bt*-maize grown plots. In summary, the authors confirmed previous conclusions on the potential entry of Cry1Ab protein from *Bt*-maize into soils which, due to environmental instability, does not accumulate. Furthermore, the microbiological analyses and molecular investigations on directly extracted DNA from soil suggested that Cry1Ab protein from natural sources may be more abundant in soils than previously assumed.
- The study of Fliessbach et al. (2012) analysed a maize Bt11 variety and its near-isogenic line along with seven conventionally bred maize varieties in climate chamber experiments. The authors analysed maize yield and quality, including fibre content, as well as soil chemical properties and microbiological parameters. The wide range of plant quality and soil-related parameters including microbial biomass and mycorrhization of roots provides an overview on the variability of environmentally relevant parameters. A one-time repeated cultivation was conducted in anticipation of potential cumulative effects. Considering that the study was conducted in climate chambers and that cultivation of the maize varieties was terminated before the plants reached the maturity state, further investigation may be needed under field conditions. Maize Bt11 values fell within the range of variation defined by the set of conventionally bred maize varieties. More specifically, there were no significant deviations seen in the fibre content or in mycorrhization. Furthermore, repeated cultivation did not add to differences between maize Bt11 and the conventionally bred varieties. The authors concluded that their study supports earlier conclusions that the effects of *Bt*-maize on soil microbiological properties are considered negligible.

6.1.6.3. Conclusion

Results reported by Margarit et al. (2008) and Fliessbach et al. (2012) do not provide new information that would invalidate the previous conclusions on interactions of maize Bt11 with biogeochemical processes and the abiotic environment made by the EFSA GMO Panel. Therefore, the EFSA GMO Panel considers that its previous conclusions on maize Bt11 remain valid and applicable.

6.1.7. Impacts of the specific cultivation, management and harvesting techniques

The consequences of changes in crop management practices associated with maize Bt11 were previously evaluated by the EFSA GMO Panel (EFSA, 2005). Recently, the outcome of this evaluation has been reviewed (EFSA, 2011a).

6.1.7.1. Summary of previous conclusions by the EFSA GMO Panel

The EFSA GMO Panel indicated that: “*apart from changes in insecticide regimes, there are no anticipated changes in management that will occur with the cultivation of maize Bt11*”. The EFSA GMO Panel noted that: “*the incidence of secondary pests and the environmental consequences of changes in management measures is highly dependent upon farming systems and regional environmental factors, and is therefore difficult to predict. Risk managers should be aware that, whenever pest management measures change, species assemblages will change accordingly and the environmental consequences should be considered in the framework of IPM in National Action Plans according to Directive 2009/128/EC*” (EFSA, 2011a).

6.1.7.2. Results from the literature search

From the literature search, no new peer-reviewed scientific publications containing evidence specific to maize Bt11 for this specific area of risk were identified.

6.1.7.3. Conclusion

In the absence of new scientific evidence specific to maize Bt11 for this specific area of risk, the EFSA GMO Panel considers that its previous conclusions on impacts of the specific cultivation, management and harvesting techniques associated with the cultivation of maize Bt11 remain valid and applicable.

6.2. Risk management strategies (including post-market environmental monitoring)

6.2.1. Risk mitigation measures

The EFSA GMO Panel previously considered that the potential risk of resistance evolution in target insect pests and that the risk of reductions in populations of certain extremely highly sensitive non-target lepidopteran species require management, and recommended the implementation of risk mitigation measures under certain conditions (EFSA, 2005, 2011a, 2012a).

6.2.1.1. Summary of previous conclusions by the EFSA GMO Panel

For target insect pests, the EFSA GMO Panel indicated that: “*appropriate Insect Resistance Management (IRM) strategies (i.e., ‘high dose/refuge’ strategy) should be employed, in order to delay the potential evolution of resistance to the Cry1Ab protein in lepidopteran target pests*”. It also made specific recommendations (in terms of sampling and target insect pest species to be considered) to the applicant to improve the proposed IRM plan (EFSA, 2011a).

For non-target Lepidoptera, the EFSA GMO Panel proposed to risk managers the implementation of risk mitigation measures to reduce pollen exposure of extremely highly sensitive non-target lepidopteran species found in maize Bt11 fields, field margins and in nearby protected habitats (EFSA, 2011d). These could include: (1) placing non-Bt-maize strips between maize Bt11 plants and field margins; (2) isolation distances to habitats where protected Lepidoptera are present (according to Directive 2004/35/EC); or (3) providing refuge areas where host-plants for Lepidoptera are not exposed to pollen from Lepidoptera-resistant maize events (EFSA, 2011a).

In EFSA (2011a), the EFSA GMO Panel indicated that: “*subject to the implementation of appropriate risk mitigation measures, the identified risks of maize Bt11 cultivation on non-target Lepidoptera can be reduced to a level of no concern. Special attention should be paid to the degree of large-scale exposure as risk mitigation measures are only needed when the proportion and uptake of maize Bt11 (and/or other Lepidoptera-resistant maize events such as maize MON 810 currently grown in the EU) are sufficiently high, regardless of the other parameters. If maize Bt11 (and/or maize MON 810) cultivation remains below 7.5% of the regional Utilized Agricultural Area^{8,9} (see www.oecd.org/), the*

⁸ For example, a maximum uptake of 25% of maize Bt11 (and/or maize MON 810) in a region where maize represents 30% or less of the arable land

global mortality is predicted to remain below 1%, even for ‘extremely sensitive’ species, and then risk mitigation measures using non-Bt-maize border rows are not required”.

Recently, the EFSA GMO Panel further supplemented its previous recommendations for risk mitigation measures by reapplying the mathematical model developed by Perry et al. (2010, 2011, 2012), in order to consider additional hypothetical agricultural conditions and to provide additional information on the factors affecting the insect resistance management plan. The EFSA GMO Panel concluded that risk mitigation measures can appropriately delay resistance evolution in target Lepidoptera, and reduce the identified risks of maize Bt11 cultivation to a level of no concern for non-target Lepidoptera (EFSA, 2012a).

6.2.1.2. Results from the literature search

From the literature search, the following new peer-reviewed scientific publication containing evidence specific to maize Bt11 for this specific area was identified and scrutinised for its possible relevance for the monitoring of maize Bt11:

- de la Poza et al. (2008) studied the genetic structure and variability of 15 field-collected Mediterranean corn borer (MCB, *Sesamia nonagrioides*) populations from Spain, France, Italy, Greece and Turkey by the aims of Random Amplified Polymorphic DNA (RAPD) markers, a simple PCR-based technique. The authors identified 65 unambiguous polymorphic markers in the analysed populations that provide indications on the genetic structure of each MCB population and to conclude on the genetic distance between the MCB populations sampled for the experiment. The likelihood of gene exchange within or among MCB populations affects the resistance evolution at local or larger level, respectively. All sampled populations were found to be significantly distant from each other. The authors confirmed earlier results on the existence of two groups: one formed by populations from Spain and the south of France and the other by populations from Greece, Italy and Turkey. The authors also observed a higher genetic distance between populations sampled at different places in northeast Spain and other Spanish populations. The authors concluded that these results suggest a limited genetic exchange between populations among relatively distant MCB populations.

6.2.1.3. Conclusion

Results reported by de la Poza et al. (2008) do not provide new information that would invalidate the previous conclusions and recommendations on the risk management measures for maize Bt11 made by the EFSA GMO Panel. Therefore, the EFSA GMO Panel considers that its previous conclusions and recommendations on maize Bt11 remain valid and applicable.

6.2.2. *Post-market environmental monitoring*

Upon request of the European Commission, the EFSA GMO Panel recently updated its previous evaluation of the initial PMEM plan for maize Bt11 and made several recommendations to strengthen the PMEM plan proposed by the applicant (EFSA, 2005, 2011a,c,d, 2012a,b,c,d,e).

6.2.2.1. Summary of previous conclusions by the EFSA GMO Panel

The EFSA GMO Panel reiterates that its earlier recommendation that appropriate IRM strategies relying on the ‘high dose/refuge’ strategy should be employed, in order to delay the potential evolution of resistance to the Cry1Ab protein in lepidopteran target pests (EFSA, 2005, 2011a). The EFSA GMO Panel recommends that there is coordination and integration of IRM and monitoring of maize Bt11 with those of other Cry1Ab-expressing maize events currently grown commercially in the EU and caution when predicting future responses of the European and Mediterranean corn borer in the EU

⁹ That is, $z_v = 0.075$, and with conservative assumptions for the other parameters $y=a=x=0.5$, yielding $R = 0.009375$

based on experiences elsewhere, as resistance evolution in target insect pests is dependent upon many factors (EFSA, 2011a, 2012a).

Regarding non-target Lepidoptera, the EFSA GMO Panel recommended case-specific monitoring (CSM) of non-target Lepidoptera only under certain exposure scenarios when maize Bt11 cultivation would present a risk to non-target Lepidoptera that are 'extremely sensitive' to the Cry1Ab protein and when the risk cannot be reduced by appropriate mitigation measures (e.g., non-Bt strips). However, in many cases, e.g., if 'extremely sensitive' species do not exist or are not present where maize Bt11 might be cultivated, the recommended risk mitigation measures may be disproportionate to the level of risk or uncertainty and put unnecessary burdens on farmers. If applicants, in agreement with risk managers, wish to reduce the proposed risk mitigation measures because they are considered too conservative, then monitoring studies may be required. The EFSA GMO Panel also suggested that, in these latter cases, further studies could be conducted to confirm the estimates of the ERA on the sensitivity of non-target Lepidoptera and whether non-target Lepidoptera larvae, with an extremely high sensitivity to the Cry1Ab protein, are present and feeding on host-plants occurring in and adjacent to maize fields at the time of pollen shed (EFSA, 2011a, 2012a,b).

With regard to general surveillance (GS), the EFSA GMO Panel requested that its proposals (e.g., farmer questionnaires, existing monitoring networks) to strengthen GS, in order to detect possible unanticipated adverse effects of maize Bt11 cultivation, are implemented (EFSA, 2011a,b,c,d,e, 2012a,d).

6.2.2.2. Results from the literature search

From the literature search, no new peer-reviewed scientific publications containing evidence specific to the PMEM of maize Bt11 were identified.

6.2.2.3. Conclusion

In the absence of new scientific evidence specific to the PMEM of maize Bt11, the EFSA GMO Panel considers that its previous conclusions and recommendations on PMEM of maize Bt11 remain valid and applicable.

OVERALL CONCLUSIONS AND RECOMMENDATIONS

Following a search of the scientific literature published between 2005 and October 2012, the EFSA GMO Panel identified 287 peer-reviewed publications containing evidence specific to the risk assessment and/or management of maize Bt11, of which 270 publications were previously discussed and cited in relevant GM maize-related applications and/or the numerous EFSA GMO Panel scientific outputs. From the remaining 17 publications, three were relevant for the food and feed safety assessment, and 14 for the environmental risk assessment and/or risk management of maize Bt11.

The EFSA GMO Panel did not identify peer-reviewed scientific publications reporting new information that would invalidate its previous conclusions on the safety of maize Bt11. Therefore, the EFSA GMO Panel considers that its previous risk assessment conclusions on maize Bt11, as well as its previous recommendations for risk mitigation measures and monitoring, remain valid and applicable.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the Deputy Director General for the Health and Consumers of the European Commission, dated 20 June 2012, to the EFSA executive Director requesting an EFSA opinion gathering all available information related to the environmental risk assessment of maize Bt11 for cultivation.
2. Acknowledgement letter, dated 11 July 2012, from the EFSA executive Director to the Director General for the Health and Consumers of the European Commission.

3. Letter, dated 27 September 2012, from the EFSA executive Director to the Director General for the Health and Consumers of the European Commission prioritising the Commission mandates in the area of GMOs currently pending with EFSA and requesting to provide additional evidence to support previous EFSA Opinions on maize 1507, Bt11 and MON 810.

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APPENDIX

A. PUBLICATIONS OBTAINED FROM ISI WEB OF KNOWLEDGE USING KEYWORD SEARCHES, AND FROM TARGETED SEARCHES OF PEER-REVIEWED JOURNALS

Authors of publication	Title of publication	Journal	Publication year	Issue in the remit of the EFSA GMO Panel and relevant to this EC mandate	Peer-reviewed publication	Publication in English	Publication previously discussed and cited in relevant GM maize-related applications and/or in scientific outputs of the EFSA GMO Panel
Accinelli C, Sacca ML, Accinelli G, Maini S	Occurrence of <i>Bacillus thuringiensis</i> harboring insecticidal cry1 genes in a corn field in Northern Italy	Agronomy for Sustainable Development	2008	NO	-	-	-
Adel-Patient K, Guimaraes VD, Paris A, Drumare MF, Ah-Leung S, Lamourette P, Nevers MC, Canlet C, Molina J, Bernard H, Creminon C, Wal JM	Immunological and metabolomic impacts of administration of Cry1Ab protein and MON 810 maize in mouse	PLoS ONE	2011	YES	YES	YES	YES
Ahmad A, Wilde GE, Zhu KY	Evaluation of effects of coleopteran-specific Cry3Bb1 protein on earthworms exposed to soil containing corn roots or biomass	Environmental Entomology	2006	NO	-	-	-
Akiyama H, Sasaki N, Sakata K, Ohmori K, Toyota A, Kikuchi Y, Watanabe T, Furui S, Kitta K, Maitani T	Indicated detection of two unapproved transgenic rice lines contaminating vermicelli products	Journal of Agricultural and Food Chemistry	2007	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Akritidis P, Pasentsis K, Tsaftaris AS, Mylona PV, Polidoros AN	Identification of unknown genetically modified material admixed in conventional cotton seed and development of an event-specific detection method	Electronic Journal of Biotechnology	2008	NO	-	-	-
Albo AG, Mila S, Digilio G, Motto M, Aime S, Corpillo D	Proteomic analysis of a genetically modified maize flour carrying cry1Ab gene and comparison to the corresponding wild-type	Maydica	2007	YES	YES	YES	YES
Alcantara EP	Postcommercialization monitoring of the long-term impact of Bt corn on non-target arthropod communities in commercial farms and adjacent riparian areas in the Philippines	Environmental Entomology	2012	YES	YES	YES	YES
Alcantara EP, Estrada A, Alpuerto V, Head G	Monitoring Cry1Ab susceptibility in Asian corn borer (Lepidoptera: Crambidae) on Bt corn in the Philippines	Crop Protection	2011	YES	YES	YES	YES
Allen KC, Pitre HN	Influence of transgenic corn expressing insecticidal protein of <i>Bacillus thuringiensis</i> Berliner on natural populations of corn earworm (Lepidoptera: Noctuidae) and southwestern corn borer (Lepidoptera: Crambidae)	Journal of Entomological Science	2006	YES	YES	YES	YES ¹⁰

¹⁰ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier/References

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Allen KC, Pitre HN	Toxicity of transgenic corn tissues expressing insecticidal protein of <i>Bacillus thuringiensis</i> Berliner to southwestern corn borer (Lepidoptera : Crambidae) in the laboratory	Journal of Entomological Science	2005	YES	YES	YES	NO
Alvarez-Alfageme F, Bigler F, Romeis J	Laboratory toxicity studies demonstrate no adverse effects of Cry1Ab and Cry3Bb1 to larvae of <i>Adalia bipunctata</i> (Coleoptera: Coccinellidae): the importance of study design	Transgenic Research	2011	YES	YES	YES	YES
Alvarez-Alfageme F, Ferry N, Castanera P, Ortego , Gatehouse Angharad MR	Prey mediated effects of Bt maize on fitness and digestive physiology of the red spider mite predator <i>Stethorus punctillum</i> Weise (Coleoptera: Coccinellidae)	Transgenic Research	2008	YES	YES	YES	YES
Alvarez-Alfageme F, Ortego F, Castanera P	Bt maize fed-prey mediated effect on fitness and digestive physiology of the ground predator <i>Poecilus cupreus</i> L. (Coleoptera: Carabidae)	Journal of Insect Physiology	2009	YES	YES	YES	YES
Alves AP, Spencer TA, Tabashnik BE, Siegfried BD	Inheritance of resistance to the Cry1Ab <i>Bacillus thuringiensis</i> toxin in <i>Ostrinia nubilalis</i> (Lepidoptera: crambidae)	Journal of Economic Entomology	2006	YES	YES	YES	YES
Andersen M Neumann, Sausse C, Lacroix B, Caul S, Messean A	Agricultural studies of GM maize and the field experimental infrastructure of ECOGEN	Pedobiologia	2007	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Anderson PL, Hellmich RL, Prasifka JR, Lewis LC	Effects on fitness and behavior of monarch butterfly larvae exposed to a combination of Cry1Ab-expressing corn anthers and pollen	Environmental Entomology	2005	YES	YES	YES	YES ¹¹
Andow DA, Farrell SL, Hu Y	Planting patterns of in-field refuges observed for Bt maize in Minnesota	Journal of Economic Entomology	2010	YES	YES	YES	YES
Andreadis SS, Alvarez-Alfageme F, Sanchez-Ramos I, Stodola TJ, Andow DA, Milonas PG, Savopoulou-Soultani M, Castanera P	Frequency of resistance to <i>Bacillus thuringiensis</i> toxin Cry1Ab in Greek and Spanish population of <i>Sesamia nonagrioides</i> (Lepidoptera: Noctuidae)	Journal of Economic Entomology	2007	YES	YES	YES	YES
Aris A	Response to comments from Monsanto scientists on our study showing detection of glyphosate and Cry1Ab in blood of women with and without pregnancy	Reproductive Toxicology	2012	YES	YES	YES	YES ¹²
Arvinth S, Arun S, Selvakesavan RK, Srikanth J, Mukunthan N, Kumar PA, Premachandran MN, Subramonian N	Genetic transformation and pyramiding of aprotinin-expressing sugarcane with cry1Ab for shoot borer (<i>Chilo infuscatellus</i>) resistance	Plant Cell Reports	2010	NO	-	-	-
Aviron S, Sanvido O, Romeis J, Herzog F, Bigler F	Case-specific monitoring of butterflies to determine potential effects of transgenic Bt-maize in Switzerland	Agriculture Ecosystems & Environment	2009	YES	YES	YES	YES

¹¹ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier/References

¹² For more details about the assessment of the original publication by the EFSA GMO Panel see letter from EFSA to the European Commission (DG Sanco) dated 19 August 2011 with reference PB/HF/AFD/mt (2011) 5863329. This letter is available upon request to EFSA. The EFSA GMO Panel notes that this commentary does not add to the risk assessment of maize MON 810.

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Babekova R, Funk T, Pecoraro S, Engel KH, Baikova D, Busch U	Duplex polymerase chain reaction (PCR) for the simultaneous detection of cryIa(b) and the maize ubiquitin promoter in the transgenic rice line KMD1	Biotechnology & Biotechnological Equipment	2008	NO	-	-	-
Babendreier D, Joller D, Romeis J, Bigler F, Widmer F	Bacterial community structures in honeybee intestines and their response to two insecticidal proteins	Fems Microbiology Ecology	2007	YES	YES	YES	YES
Babendreier D, Kalberer NM, Romeis J, Fluri P, Mulligan E, Bigler F	Influence of Bt-transgenic pollen Bt-toxin and protease inhibitor (SBTI) ingestion on development of the hypopharyngeal glands in honeybees	Apidologie	2005	YES	YES	YES	YES
Badea EM, Chelu F, Lacatusu A	Results regarding the levels of Cry1Ab protein in transgenic corn tissue (MON810) and the fate of Bt protein in three soil types	Romanian Biotechnological Letters	2010	YES	YES	YES	YES
Badea EM, Pamfil D	The status of agricultural biotechnology and biosafety in Romania.	Bulletin of university of Agricultural sciences and veterinary medicine cluj- napoca. Animal Science and Biotechnologies	2009	NO	-	-	-
Bai YY, Jiang MX, Cheng JA, Wang D	Effects of CryIAb toxin on <i>Propylea japonica</i> (Thunberg) (Coleoptera: Coccinellidae) through its prey <i>Nilaparvata lugens</i> St(a)over-circle1 (Homoptera: Delphacidae) feeding on transgenic Bt rice	Environmental Entomology	2006	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Bai YY, Yan RH, Ye GY, Huang FN, Cheng JA	Effects of transgenic rice expressing <i>Bacillus thuringiensis</i> Cry1Ab protein on ground-dwelling collembolan community in postharvest seasons	Environmental Entomology	2010	NO	-	-	-
Bakonyi G, Dolezsai A, Matrai N, Szekacs A	Effects of consumption of Bt-maize (MON 810) on the collembolan <i>Folsomia candida</i> over multiple generations: a laboratory study	Insects	2011	YES	YES	YES	YES
Bakonyi G, Szira F, Kiss I, Villanyi I, Seres A, Szekacs A	Preference tests with collembolas on isogenic and Bt-maize	European Journal of Soil Biology	2006	YES	YES	YES	YES ¹³
Balog A, Kiss J, Szekeres D, Szenasi A, Marko V	Rove beetle (Coleoptera: Staphylinidae) communities in transgenic Bt (MON810) and near isogenic maize	Crop Protection	2010	YES	YES	YES	YES
Balog A, Szenasi A, Szekeres D, Kiss J	Staphylinids (Coleoptera: Staphylinidae) in genetically modified maize ecosystems: species densities and trophic interactions	IOBC/WPRS Bulletin	2010	YES	NO	-	-
Baniulis D, Sikorskaite S, Bendokas V, Staniene G, Gelvonauskiene D, Stanys V	Application of proteolytic digestion test to assess allergenicity risk of genetically modified plants	Sodininkyste ir darzininkyste	2011	YES	YES	NO	-
Barriuso J, Valverde JR, Mellado RP	Effect of Cry1Ab protein on rhizobacterial communities of Bt-maize over a four-year cultivation period	PLoS ONE	2012	YES	YES	YES	YES

¹³ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier/Appendices

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Bashir K, Husnain T, Fatima T, Riaz N, Makhdoom R, Riazuddin S	Novel indica basmati line (B-370) expressing two unrelated genes of <i>Bacillus thuringiensis</i> is highly resistant to two lepidopteran insects in the field	Crop Protection	2005	NO	-	-	-
Batista R, Nunes B, Carmo M, Cardoso C, Jose HS, de Almeida AB, Manique A, Bento L, Ricardo CP, Oliveira MM	Lack of detectable allergenicity of transgenic maize and soya samples	Journal of Allergy and Clinical Immunology	2005	YES	YES	YES	YES ¹⁴
Baumgarte S, Tebbe CC	Field studies on the environmental fate of the Cry1Ab Bt-toxin produced by transgenic maize (MON810) and its effect on bacterial communities in the maize rhizosphere	Molecular Ecology	2005	YES	YES	YES	YES
Beagle JM, Apgar GA, Jones KL, Griswold KE, Radcliffe JS, Qiu X, Lightfoot DA, Iqbal MJ	The digestive fate of <i>Escherichia coli</i> glutamate dehydrogenase deoxyribonucleic acid from transgenic corn in diets fed to weanling pigs	Journal of Animal Science	2006	NO	-	-	-
Bel Y, Siqueira HAA, Siegfried BD, Ferre J, Escriche B	Variability in the cadherin gene in an <i>Ostrinia nubilalis</i> strain selected for Cry1Ab resistance	Insect Biochemistry and molecular Biology	2009	YES	YES	YES	YES
Beres PK	Harmfulness of <i>Ostrinia nubilalis</i> Hbn. on some non-Bt versus genetically modified Bt maize (<i>Zea mays</i> L.) cultivars in Poland in 2006-2007	Journal of Plant Protection Research	2010	YES	YES	YES	YES

¹⁴ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Specific information

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Beres PK	Reduction of damage caused by <i>Ostrinia nubilalis</i> Hbn. in south-eastern Poland in 2007 through the cultivation of transgenic maize varieties	IOBC/WPRS Bulletin	2010	YES	NO	-	-
Birch ANE, Griffiths BS, Caul S, Thompson J, Heckmann LH, Krogh PH, Cortet J	The role of laboratory glasshouse and field scale experiments in understanding the interactions between genetically modified crops and soil ecosystems: a review of the ECOGEN project	Pedobiologia	2007	YES	YES	YES	YES
Biro B, Villanyi I, Fuzy A, Naar Z	Bacterial and fungal colonization in the rhizosphere of genetically modified (Bt) and isogenic control maize	Agrokemia es talajtan	2005	YES	YES	NO	-
Bohn T, Primicerio R, Hessen DO, Traavik T	Reduced fitness of <i>Daphnia magna</i> fed a Bt-transgenic maize variety	Archives of Environmental Contamination and Toxicology	2008	YES	YES	YES	YES
Bohn T, Traavik T, Primicerio R	Demographic responses of <i>Daphnia magna</i> fed transgenic Bt-maize	Ecotoxicology	2010	YES	YES	YES	YES
Bondzio A, Stumpff F, Schoen J, Martens H, Einspanier R	Impact of <i>Bacillus thuringiensis</i> toxin Cry1Ab on rumen epithelial cells (REC) - A new in vitro model for safety assessment of recombinant food compounds	Food and Chemical Toxicology	2008	YES	YES	YES	YES ¹⁵

¹⁵ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-12-05_add info under RA/References

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Bordoni R, Germini A, Mezzelani A, Marchelli R, De Bellis G	A microarray platform for parallel detection of five transgenic events in foods: A combined polymerase chain reaction - ligation detection reaction - universal array method	Journal of Agricultural and Food Chemistry	2005	NO	-	-	-
Bruns Hd, Abel Craig A	Effects of nitrogen fertility on Bt endotoxin levels in maize	Journal of Entomological Science	2007	NO	-	-	-
Buitenhuis AJ, Lund MS, Thomasen JR, Thomsen B, Nielsen V Hunnicke, BC, Guldbrandtsen B	Detection of quantitative trait loci affecting lameness and leg conformation traits in Danish Holstein cattle	Journal of Dairy Science	2007	NO	-	-	-
Buntin GD	Corn expressing Cry1Ab endotoxin for management of fall armyworm and corn earworm (Lepidoptera: Noctuidae) in silage production	Journal of Entomological Science	2010	YES	YES	YES	YES
Burgio G, Lanzoni A, Accinelli G, Dinelli G, Bonetti A, Marotti I, Ramilli F	Evaluation of Bt-toxin uptake by the non-target herbivore <i>Myzus persicae</i> (Hemiptera: Aphididae) feeding on transgenic oilseed rape	Bulletin of Entomological Research	2007	NO	-	-	-
Burkness EC, O'Rourke PK, Hutchison WD	Cross-Pollination of nontransgenic corn ears with transgenic Bt corn: efficacy against lepidopteran pests and implications for resistance management	Journal of Economic Entomology	2011	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Burkness Eric C, Dively Galen, Patton Terry, Morey Amy C, Hutchison William D	Novel Vip3A <i>Bacillus thuringiensis</i> (Bt) maize approaches high-dose efficacy against <i>Helicoverpa zea</i> (Lepidoptera: Noctuidae) under field conditions: Implications for resistance management	GM Crops	2010	YES	YES	YES	NO
Buzoianu SG, Walsh MC, Rea MC, O'Sullivan O, Cotter PD, Ross RP, Gardiner GE, Lawlor PG	High-throughput sequence-based analysis of the intestinal microbiota of weanling pigs fed genetically modified MON810 maize expressing <i>Bacillus thuringiensis</i> Cry1Ab (Bt maize) for 31 days	Applied and Environmental Microbiology	2012	YES	YES	YES	YES
Cagan L, Barta M	Sublethal effect of Bt-maize in semi-artificial diet on European corn borer larvae <i>Ostrinia nubilalis</i> (Hubner 1796) (Lepidoptera Crambidae)	IOBC/WPRS Bulletin	2008	YES	NO	-	-
Calsamiglia S, Hernandez B, Hartnell GF, Phipps R	Effects of corn silage derived from a genetically modified variety containing two transgenes on feed intake milk production and composition and the absence of detectable transgenic deoxyribonucleic acid in milk in holstein dairy cows	Journal of Dairy Science	2007	YES	YES	YES	YES ¹⁶

¹⁶ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/ 2008-12-05_add info under RA/References

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Campa R, Hooker D, Miller JD, Schaafsma A, Hammond B	Modeling effects of Environment insect damage and Bt genotypes on fumonisin accumulation in maize in Argentina and the Philippines	Mycopathologia	2005	NO	-	-	-
Castaldini M, Turrini A, Sbrana C, Benedetti A, Marchionni M, Mocali S, Fabiani A, Landi S, Santomassimo F, Pietrangeli B, Nuti M, Miclaus N, Giovannetti M	Impact of Bt corn on rhizospheric and on beneficial mycorrhizal symbiosis and soil eubacterial communities in experimental microcosms	Applied and Environmental Microbiology	2005	YES	YES	YES	YES ¹⁷
Catangui MA, Berg RK	Western bean cutworm <i>Striacosta albicosta</i> (Smith) (Lepidoptera: Noctuidae) as a potential pest of transgenic Cry1Ab <i>Bacillus thuringiensis</i> corn hybrids in South Dakota	Environmental Entomology	2006	YES	YES	YES	YES
Chabaca R, Larwence A, Hamadache A	Live stock and cereal production in Algeria: choice of varieties with best grain yield and a straw of good feed value	Livestock Research for Rural Development	2009	NO	-	-	-
Chambers CP, Whiles MR, Rosi-Marshall EJ, Tank JL, Royer TV, Griffiths NA, Evans-White MA, Stojak AR	Responses of stream macroinvertebrates to Bt maize leaf detritus	Ecological Applications	2010	YES	YES	YES	YES
Chang X, Chang XY, He KL, Wang ZY, Bai SX	Resistance evaluation of transgenic Bt maize to Oriental armyworm	Acta Phytophylacica Sinica	2007	YES	YES	NO	-

¹⁷ GM plant market notification with reference C/F/96/05.10/2011.05.30_add data/Response to the EFSA request for additional information on the application C/F/96/05.10 of Bt11 maize cultivation/Appendix 2 - Literature Review: Bt11 maize studies on NTOs

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Chang XY, He KLi, Wang ZY, Bai SX	Evaluation of transgenic Bt maize for resistance to cotton bollworm	Acta Phytophylacica Sinica	2006	YES	YES	NO	-
Cheeke TE, Pace BA, Rosenstiel TN, Cruzan MB	The influence of fertilizer level and spore density on arbuscular mycorrhizal colonization of transgenic Bt11 maize (<i>Zea mays</i>) in experimental microcosms	FEMS Microbiology Ecology	2011	YES	YES	YES	YES
Cheeke TE, Rosenstiel Todd N, Cruzan MB	Evidence of reduced arbuscular mycorrhizal fungal colonization in multiple lines of Bt maize	American Journal of Botany	2012	YES	YES	YES	YES
Chen L, Guo J, Wang Q, Kai G, Yang L	Development of the visual loop-mediated isothermal amplification assays for seven genetically modified maize events and their application in practical samples analysis	Journal of Agricultural and Food Chemistry	2011	NO	-	-	-
Chen M, Ye G, Liu Z, Fang Q, Hu C, Peng Y, Shelton AM	Analysis of Cry1Ab toxin bioaccumulation in a food chain of Bt rice an herbivore and a predator	Ecotoxicology	2009	NO	-	-	-
Chilcutt CF, Odvody GN, Correa JC, Remmers J	Effects of <i>Bacillus thuringiensis</i> transgenic corn on corn earworm and fall armyworm (Lepidoptera: Noctuidae) densities	Journal of Economic Entomology	2007	YES	YES	YES	NO

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Chunjiao Z, Wentao X, Zhifang Z, Yunbo L, Xinghua Y, Nan Z, Kunlun H	Universal primer-multiplex-polymerase chain reaction (UP-M-PCR) and capillary electrophoresis-laser-induced fluorescence analysis for the simultaneous detection of six genetically modified maize lines	Journal of Agricultural and Food Chemistry	2011	NO	-	-	-
Ciuca M	A preliminary report on the identification of SSR markers for bunt (<i>Tilletia</i> sp.) resistance in wheat	Czech Journal of Genetics and Plant Breeding	2011	NO	-	-	-
Ciuca M, Ittu M, Oncica F, Tezel-Mateescu R, Cornea CP, Iuoras M	Researches concerning the use of molecular techniques based on PCR in wheat breeding for common bunt resistance (<i>Tilletia</i> sp.)	Probleme de Denetica Teoretica si Aplicata	2007	NO	-	-	-
Clark BW, Coats JR	Subacute effects of Cry1Ab Bt corn litter on the earthworm <i>Eisenia fetida</i> and the springtail <i>Folsomia candida</i>	Environmental Entomology	2006	YES	YES	YES	YES ¹⁸
Clark BW, Prihoda KR, Coats JR	Subacute effects of transgenic Cry1Ab <i>Bacillus thuringiensis</i> corn litter on the isopods <i>Trachelipus rathkii</i> and <i>Armadillidium nasatum</i>	Environmental Toxicology and Chemistry	2006	YES	YES	YES	YES ¹⁹
Cole JB, Wiggans GR, Ma L, Sonstegard TS, Lawlor TJ, Crooker BA, van Tassell CP, Yang J, Wang SW, Matukumalli LK, Da Y	Genome-wide association analysis of thirtyone production health reproduction and body conformation traits in contemporary US Holstein cows	BMC Genomics	2011	NO	-	-	-

¹⁸ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier/References

¹⁹ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier/References

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Cortet J, Andersen MN, Caul S, Griffiths B, Joffe R, Lacroix B, Sausse C, Thompson J, Krogh PH	Decomposition processes under Bt (<i>Bacillus thuringiensis</i>) maize: results of a multi-site experiment	Soil Biology & Biochemistry	2006	YES	YES	YES	YES
Cortet J, Griffiths BS, Bohanec M, Demsar D, Andersen MN, Caul S, Birch ANE, Pernin C, Tabone E, de Vauflery A, Ke X, Krogh PH	Evaluation of effects of transgenic Bt maize on microarthropods in a European multi-site experiment	Pedobiologia	2007	YES	YES	YES	YES
Cota LC, Botez C, Pamfil D, Grigoras MA	Testing of RAPD and SSR markers for wheat resistance to <i>Tilletia</i> spp. in F2 segregating populations	Proceedings abstract	2010	NO	-	-	-
Cota LC, Pamfil D, Botez C, Grigoras M	Preliminary studies on microsatellite marker analysis of resistance to common bunt in several wheat genotypes (<i>Triticum aestivum</i> L.)	Notulae Botanicae Horti Agrobotanici Cluj-Napoca	2010	NO	-	-	-
Crava CM, Bel Y, Ferre J, Escriche B	Absence of Cry1Ab resistance in a Spanish <i>Ostrinia nubilalis</i> population from an infested greenhouse	IOBC/WPRS Bulletin	2010	YES	NO	-	-
Crava MC, Bel Y, Escriche B	<i>Bacillus thuringiensis</i> susceptibility variation among <i>Ostrinia nubilalis</i> populations	IOBC/WPRS Bulletin	2009	YES	NO	-	-
Crespo ALB, Rodrigo-Simon A, Siqueira HAA, Pereira EJG, Ferre J, Siegfried BD	Cross-resistance and mechanism of resistance to Cry1Ab toxin from <i>Bacillus thuringiensis</i> in a field-derived strain of European corn borer <i>Ostrinia nubilalis</i>	Journal of Invertebrate Pathology	2011	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Crespo ALB, Spencer TA, Alves AP, Hellmich RL, Blankenship EE, Magalhaes LC, Siegfried BD	On-plant survival and inheritance of resistance to Cry1Ab toxin from <i>Bacillus thuringiensis</i> in a field-derived strain of European corn borer <i>Ostrinia nubilalis</i>	Pest Management Science	2009	YES	YES	YES	YES
Crespo ALB, Spencer TA, Nekl E, Pusztai-Carey M, Moar WJ, Siegfried BD	Comparison and validation of methods to quantify Cry1Ab toxin from <i>Bacillus thuringiensis</i> for standardization of insect bioassay	Applied and Environmental Microbiology	2008	NO			
Crespo ALB, Spencer TA, Tan Sek Y, Siegfried BD	Fitness costs of Cry1Ab resistance in a field-derived strain of <i>Ostrinia nubilalis</i> (Lepidoptera: Crambidae)	Journal of Economic Entomology	2010	YES	YES	YES	YES
Custodio MG, Powers WJ, Huff-Lonergan E, Faust MA, Stein J	Growth, pork quality, and excretion characteristics of pigs fed Bt corn or non-transgenic corn	Canadian Journal of Animal Science	2006	YES	YES	YES	YES ²⁰
Czapla A, Kurczak P, Kiekiewicz M	The rose-grain aphid (<i>Metopolophium dirhodum</i> Walker) bionomy parameters on chosen maize cultivars	Progress in Plant Protection	2011	YES	YES	NO	-
Dalmacio SC, Lugod TR, Serrano EM, Munkvold GP	Reduced incidence of bacterial rot on transgenic insect-resistant maize in the Philippines	Plant Disease	2007	YES	YES	YES	NO
Daly T, Buntin GD	Effect of <i>Bacillus thuringiensis</i> transgenic corn for lepidopteran control on nontarget arthropods	Environmental Entomology	2005	YES	YES	YES	YES ²¹

²⁰ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/ 2008-12-05_add info under RA/References

²¹ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Darvas B, Banati H, Takacs E, Lauber E, Szecsi A, Szekacs A	Relationships of <i>Helicoverpa armigera</i> <i>Ostrinia nubilalis</i> and <i>Fusarium verticillioides</i> on MON 810 maize	Insects	2011	YES	YES	YES	YES
Daudu CK, Muchaonyerwa P, Mkeni PNS	Litterbag decomposition of genetically modified maize residues and their constituent <i>Bacillus thuringiensis</i> protein (Cry1Ab) under field conditions in the central region of the Eastern Cape South Africa	Agriculture Ecosystems & Environment	2009	YES	YES	YES	YES
de La Poza M, Farinos GP, Beroiz B, Ortego F, Hernandez-Crespo P, Castanera P	Genetic structure of <i>Sesamia nonagrioides</i> (Lefebvre) Populations in the Mediterranean area	Environmental Entomology	2008	YES	YES	YES	NO
de la Poza M, Pons X, Farinos GP, Lopez C, Ortego F, Eizaguirre M, Castanera P, Albajes R	Impact of farm-scale Bt maize on abundance of predatory arthropods in Spain	Crop Protection	2005	YES	YES	YES	YES ²²
De Lorenzi L, De Giovanni A, Molteni L, Denis C, Eggen A, Parma P	Characterization of a balanced reciprocal translocation rcp(9;11)(q27;q11) in cattle	Cytogenetic and Genome Research	2007	NO	-	-	-
de Polania IZ, Alvarez Alcaraz G	Analysis of the influence on the main beneficial fauna by two transgenic cultivars cotton and corn at El Espinal (Tolima).	Revista u.d.c.a. Actualidad & divulgacion cientifica	2008	YES	YES	NO	-

²² GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier/Appendices

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
de Polania IZ, Arevalo H A, Mejia R	The fall armyworm <i>Spodoptera frugiperda</i> (J.E. Smith) (Lepidoptera: Noctuidae) and some transgenic plants	Revista colombiana de ciencias horticolas	2007	YES	YES	NO	-
de Polania IZ, de, Arevalo Maldonado HA, Mejia Cruz RJL	<i>Spodoptera frugiperda</i> : response of different populations to the Cry1Ab toxin	Revista colombiana de entomologia	2009	YES	YES	NO	-
de Vaufleury A, Kramarz PE, Binet P, Cortet J, Caul S, Andersen MN, Plumey E, Coeurdassier M, Krogh PH	Exposure and effects assessments of Bt-maize on non-target organisms (gastropods microarthropods mycorrhizal fungi) in microcosms	Pedobiologia	2007	YES	YES	YES	YES
Debeljak M, Cortet J, Demsar D, Krogh PH, Dzeroski S	Hierarchical classification of environmental factors and agricultural practices affecting soil fauna under cropping systems using Bt maize	Pedobiologia	2007	YES	YES	YES	YES ²³
Diaz-Mendoza M, Farinos GP, Castanera P, Hernandez-Crespo P, Ortego F	Proteolytic processing of native Cry1Ab toxin by midgut extracts and purified trypsins from the Mediterranean corn borer <i>Sesamia nonagrioides</i>	Journal of Insect Physiology	2007	YES	YES	YES	YES ²⁴
Digilio MC, Sasso R, Di Leo MG, Iodice L, Monti MM, Santeramo R, Arpaia S, Guerrieri E	Interactions between Bt-expressing tomato and non-target insects: the aphid <i>Macrosiphum euphorbiae</i> and its natural enemies	Journal of Plant Interactions	2012	NO	-	-	-

²³ GM plant market notification with reference C/F/96/05.10/2011.05.30_add data/Response to the EFSA request for additional information on the application C/F/96/05.10 of Bt11 maize cultivation/Appendix 2 - Literature Review: Bt11 maize studies on NTOs

²⁴ GM plant market registration application with reference EFSA-GMO-BE-2010-79/Application/CD 1 (nCI)/Appendices nCI

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Dinon AZ, Bosco KT, Arisi ACM	Monitoring of Bt11 and Bt176 genetically modified maize in food sold commercially in Brazil from 2005 to 2007	Journal of the science of food and agriculture	2010	NO	-	-	-
Dinon AZ, de Melo JE, Arisi ACM	Monitoring of MON810 genetically modified maize in foods in Brazil from 2005 to 2007	Journal of Food Composition and Analysis	2008	NO	-	-	-
Dively GP	Impact of transgenic VIP3A x Cry1Ab lepidopteran-resistant field corn on the nontarget arthropod community	Environmental Entomology	2005	YES	YES	YES	YES ²⁵
Doerries HH, Remus I, Groenewald A, Groenewald C, Berghof-Jaeger K	Development of a qualitative, multiplex real-time PCR kit for screening of genetically modified organisms (GMOs)	Analytical and bioanalytical chemistry	2010	NO	-	-	-
Dorhout DL, Rice ME	Intraguild competition and enhanced survival of western bean cutworm (Lepidoptera: Noctuidae) on transgenic Cry1Ab (MON810) <i>Bacillus thuringiensis</i> corn	Journal of Economic Entomology	2010	YES	YES	YES	YES
Douville M, Gagne F, Andre C, Blaise C	Occurrence of the transgenic corn cry1Ab gene in freshwater mussels (<i>Elliptio complanata</i>) near corn fields: Evidence of exposure by bacterial ingestion	Ecotoxicology and Environmental Safety	2009	YES	YES	YES	YES
Douville M, Gagne F, Blaise C, Andre C	Occurrence and persistence of <i>Bacillus thuringiensis</i> (Bt) and transgenic Bt corn cry1Ab gene from an aquatic Environment	Ecotoxicology and Environmental Safety	2007	YES	YES	YES	YES

²⁵ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier/Appendices

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Douville M, Gagne F, Masson L, McKay J, Blaise C	Tracking the source of <i>Bacillus thuringiensis</i> Cry1Ab endotoxin in the Environment	Biochemical systematics and Ecology	2005	YES	YES	YES	YES
Duan JJ, Paradise MS, Lundgren JG, Bookout JT, Jiang CJ, Wiedenmann RN	Assessing nontarget impacts of Bt corn resistant to corn rootworms: Tier-1 testing with larvae of <i>Poecilus chalcites</i> (Coleoptera: Carabidae)	Environmental Entomology	2006	YES	YES	YES	YES
Dubelman S, Ayden BR, Bader BM, Brown CR, Jiang CJ, Vlachos D	Cry1Ab protein does not persist in soil after 3 years of sustained Bt corn use	Environmental Entomology	2005	YES	YES	YES	YES ²⁶
Dumalasova V, Bartos P	Wheat breeding for common and dwarf bunt resistance - marker assisted selection?	Proceedings abstract	2010	NO	-	-	-
Dutra CC, Koch RL, Burkness EC, Meissle M, Romeis J, Hutchison WD, Fernandes MG	<i>Harmonia axyridis</i> (Coleoptera: Coccinellidae) exhibits no preference between Bt and non-Bt maize fed <i>Spodoptera frugiperda</i> (Lepidoptera: Noctuidae)	PLoS ONE	2012	YES	YES	YES	YES
Dutton A, Romeis J, Bigler F	Effects of Bt maize expressing Cry1Ab and Bt spray on <i>Spodoptera littoralis</i>	Entomologia Experimentalis et Applicata	2005	YES	YES	YES	YES
Dyer GA, Serratos-Hernandez JA, Perales HR, Gepts P, Pineyro-Nelson A, Chavez A, Salinas-Arreortua N, Yunez-Naude A, Taylor J E, Alvarez-Buylla ER	Dispersal of transgenes through maize seed systems in Mexico	PLoS ONE	2009	NO	-	-	-

²⁶ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Eichenseer H, Strohheln R, Burks J	Frequency and severity of western bean cutworm (Lepidoptera: Noctuidae) ear damage in transgenic corn hybrids expressing different <i>Bacillus thuringiensis</i> cry toxins	Journal of Economic Entomology	2008	YES	YES	YES	YES
Eizaguirre M, Albajes R, Lopez C, Eras J, Lumbierres B, Pons X	Six years after the commercial introduction of Bt maize in Spain: field evaluation impact and future prospects	Transgenic Research	2006	YES	YES	YES	YES ²⁷
Eizaguirre M, Madeira F, Lopez C	Effects of Bt maize on non-target lepidopteran pests	IOBC/WPRS Bulletin	2010	YES	NO	-	-
Emmerling C, Strunk H, Schoebinger U, Schrader S	Fragmentation of Cry1Ab protein from Bt-maize (MON810) through the gut of the earthworm species <i>Lumbricus terrestris</i> L.	European Journal of Soil Biology	2011	YES	YES	YES	YES
Engels H, Bourguet D, Cagan L, Manachini B, Schuphan I, Stodola TJ, Micoud A, Brazier C, Mottet C, Andow DA	Evaluating resistance to Bt toxin Cry1Ab by F-2 screen in European populations of <i>Ostrinia nubilalis</i> (Lepidoptera: Crambidae)	Journal of Economic Entomology	2010	YES	YES	YES	YES
Erasmus A, Van Rensburg JBJ, Van Den Berg J	Effects of Bt maize on <i>Agrotis segetum</i> (Lepidoptera: Noctuidae): a pest of maize seedlings	Environmental Entomology	2010	YES	YES	YES	YES
Ermolli M, Fantozzi A, Marini M, Scotti D, Balla B, Hoffmann S, Querci M, Paoletti C, Van den Eede G	Food safety: screening tests used to detect and quantify GMO proteins	Accreditation and Quality Assurance	2006	NO	-	-	-

²⁷ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Ermolli M, Prospero A, Balla B, Querci M, Mazzeo A, Van Den Eede G	Development of an innovative immunoassay for CP4EPSPS and Cry1AB genetically modified protein detection and quantification	Food additives and contaminants	2006	NO	-	-	-
Fantozzi A, Ermolli M, Marini M, Scotti D, Balla B, Querci M, Langrell SRH, Van den Eede G	First application of a microsphere-based immunoassay to the detection of genetically modified organisms (GMOs): quantification of Cry1Ab protein in genetically modified maize	Journal of Agricultural and Food Chemistry	2007	NO	-	-	-
Farinos GR, Andreadis SS, de la Poza M, Mironidis GK, Ortego F, Savopoulou-Soultani M, Castanera P	Comparative assessment of the field-susceptibility of <i>Sesamia nonagrioides</i> to the Cry1Ab toxin in areas with different adoption rates of Bt maize and in Bt-free areas	Crop Protection	2011	YES	YES	YES	YES
Farrar RR, Shepard BM, Shapiro M, Hassell RL, Schaffer ML, Smith CM	Supplemental control of lepidopterous pests on Bt transgenic sweet corn with biologically-based spray treatments	Journal of Insect Science (Madison)	2009	NO	-	-	-
Fatoretto JC, Sena JAD, Barreto MR, Lemos MVF, Junior Arlindo LB	Association of bioassays and molecular characterization to select new <i>Bacillus thuringiensis</i> isolates - Effective against <i>Spodoptera frugiperda</i> J. E. Smith (Lepidoptera: Noctuidae)	Neotropical Entomology	2007	YES	YES	NO	-
Felke M, Langenbruch G A	Susceptibility of European corn borer larvae to pollen of Bt.-176 maize	Nachrichtenblatt des deutschen pflanzenschutzdienstes	2008	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Feng YJ, Jin Q, Wang JW	Systemic induced effects of mechanical wounding on the chemical defence of Bt corn (<i>Zea mays</i>)	Chinese Journal of Plant Ecology	2010	NO	-	-	-
Fernandes OA, Faria M, Martinelli S, Schmidt F, Carvalho VF, Moro G	Short-term assessment of Bt maize on non-target arthropods in Brazil	Scientia Agricola	2007	YES	YES	YES	YES ²⁸
Flannagan RD, Yu CG, Mathis JP, Meyer TE, Shi XM, Siqueira HAA, Siegfried BD	Identification cloning and expression of a Cry1Ab cadherin receptor from European corn borer <i>Ostrinia nubilalis</i> (Hubner) (Lepidoptera : Crambidae)	Insect Biochemistry and molecular Biology	2005	NO	-	-	-
Fliessbach A, Messmer M, Nietlispach B, Infante V, Maeder P	Effects of conventionally bred and <i>Bacillus thuringiensis</i> (Bt) maize varieties on soil microbial biomass and activity	Biology and Fertility of Soils	2012	YES	YES	YES	NO
Flores S, Saxena D, Stotzky G	Transgenic Bt plants decompose less in soil than non-Bt plants	Soil Biology & Biochemistry	2005	YES	YES	YES	YES
Folloni S, Bellocchi G, Kagkli DM, Pastor-Benito S, Aguilera M, Mazzeo A, Querci M, Van den Eede G, Ermolli M	Development of an ELISA reverse-based assay to assess the presence of mycotoxins in cereal flour	Food Analytical Methods	2011	NO	-	-	-
Freier B, Schorling M, Schober A	The associates of European corn borer	Nachrichtenblatt des deutschen pflanzenschutzdienstes	2007	YES	YES	NO	-
Fu Q, Zhang Y, Huang W, Hu H, Chen D, Yang C	Remaining dynamics of Cry1Ab proteins from transgenic Bt corn in soil	Journal of Food agriculture & Environment	2012	NO	-	-	-

²⁸ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Galeano P, Debat CM, Ruibal F, Fraguas LF, Galvan GA	Cross-fertilization between genetically modified and non-genetically modified maize crops in Uruguay	Environmental Biosafety Research	2010	YES	YES	YES	YES
Garcia M, Ortego F, Castanera P, Farinos GP	Effects of exposure to the toxin Cry1Ab through Bt maize fed-prey on the performance and digestive physiology of the predatory rove beetle <i>Atheta coriaria</i>	Biological Control	2010	YES	YES	YES	YES
Gassmann AJ, Petzold-Maxwell JL, Keweshan RS, Dunbar MW	Western corn rootworm and Bt maize: challenges of pest resistance in the field	GM Crops and Food Biotechnology in Agriculture and the Food Chain	2012	NO	-	-	-
Gathmann A, Wirooks L, Hothorn LA, Bartsch D, Schuphan I	Impact of Bt maize pollen (MON810) on lepidopteran larvae living on accompanying weeds	Molecular Ecology	2006	YES	YES	YES	YES ²⁹
George DM, RF Claire, Bendall MW, Taylor MA, Gatehouse Angharad MR	Developmental studies of transgenic maize expressing Cry1Ab on the African stem borer <i>Busseola fusca</i> ; effects on midgut cellular structure	Pest Management Science	2012	YES	YES	YES	YES
Germini A, Rossi S, Zanetti A, Corradini R, Fogher C, Marchelli R	Development of a peptide nucleic acid array platform for the detection of genetically modified organisms in food	Journal of Agricultural and Food Chemistry	2005	NO	-	-	-
Germini A, Salati C, Quartaroli G, Marchelli R	Determination of transgenic material on the Italian food market using a new multiplex PCR method	Italian Journal of Food Science	2005	NO	-	-	-

²⁹ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Ghasimi HZ, Rahnama H, Panahandeh J, Baghban KRB, Arab JKM, Mahna N	Green-tissue-specific C(4)-PEPC-promoter-driven expression of Cry1Ab makes transgenic potato plants resistant to tuber moth (<i>Phthorimaea operculella</i> Zeller).	Plant Cell Reports	2009	NO	-	-	-
Ghimire MN, Huang F, Leonard R, Head Graham P, Yang Y	Susceptibility of Cry1Ab-susceptible and resistant sugarcane borer to transgenic corn plants containing single or pyramided <i>Bacillus thuringiensis</i> genes	Crop Protection	2011	YES	YES	YES	YES
Giovannoli C, Anfossi L, Baggiani C, Giraudi G	Binding properties of a monoclonal antibody against the Cry1Ab from <i>Bacillus Thuringiensis</i> for the development of a capillary electrophoresis competitive immunoassay	Analytical and bioanalytical Chemistry	2008	NO			
Goates Blair J	Identification of new pathogenic races of common bunt and dwarf bunt fungi, and evaluation of known races using an expanded set of differential wheat lines	Plant Disease	2012	NO	-	-	-
Goggi AS, Caragea P, Lopez-Sanchez H, Westgate M, Arritt R, Clark C	Statistical analysis of outcrossing between adjacent maize grain production fields	Field Crops Research	2006	NO			
Gomez I, Arenas I, Pacheco S, Bravo A, Soberon M	New insights into the mode of action of Cry1Ab toxin used in transgenic insect-resistant crops	Southwestern Entomologist	2010	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Gonzalez-Cabrera J, Farinos GP, Caccia S, Diaz-Mendoza M, Castanera P, Leonardi MG, Giordana B, Ferre J	Toxicity and mode of action of <i>Bacillus thuringiensis</i> cry proteins in the Mediterranean corn borer <i>Sesamia nonagrioides</i> (Lefebvre)	Applied and Environmental Microbiology	2006	YES	YES	YES	YES
Gonzalez-Zamora J E, Camunez S, Avilla C	Effects of <i>Bacillus thuringiensis</i> cry toxins on developmental and reproductive characteristics of the predator <i>Orius albidipennis</i> (Hemiptera : Anthocoridae) under laboratory conditions	Environmental Entomology	2007	YES	YES	YES	YES ³⁰
Gorecka J, Dabrowski Z T, Godzina M, Kubis K	Validation of some techniques used in the evaluation of GM plant effects on tri-trophic interactions	IOBC/WPRS Bulletin	2008	YES	NO	-	-
Greiner R, Konietzny U	Presence of genetically modified maize and soy in food products sold commercially in Brazil from 2000 to 2005	Food Control	2008	NO	-	-	-
Greiner R, Konietzny U, Villavicencio ALCH	Qualitative and quantitative detection of genetically modified maize and soy in processed foods sold commercially in Brazil by PCR-based methods	Food Control	2005	NO	-	-	-
Griffiths BS, Caul S, Thompson J, Birch ANE, Scrimgeour C, Cortet J, Foggo A, Hackett CA, Krogh PH	Soil microbial and faunal community responses to Bt maize and insecticide in two soils	Journal of Environmental Quality	2006	YES	YES	YES	YES

³⁰ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Griffiths BS, Heckmann LH, Caul S, Thompson J, Scrimgeour C, Krogh PH	Varietal effects of eight paired lines of transgenic Bt maize and near-isogenic non-Bt maize on soil microbial and nematode community structure	Plant Biotechnology Journal	2007	YES	YES	YES	YES
Gruber H, Paul V, Guertler P, Spiekers H, Tichopad A, Meyer HHD, Mueller M	Fate of Cry1Ab protein in agricultural systems under slurry management of cows fed genetically modified maize (<i>Zea mays</i> L.) MON810: a quantitative assessment	Journal of Agricultural and Food Chemistry	2011	YES	YES	YES	YES
Gruber H, Paul V, Meyer HHD, Mueller M	Determination of insecticidal Cry1Ab protein in soil collected in the final growing seasons of a nine-year field trial of Bt-maize MON810	Transgenic Research	2012	YES	YES	YES	YES
Gruber H, Paul V, Meyer HHD, Mueller M	Validation of an enzyme immunoassay for monitoring Cry1Ab toxin in soils planted with Bt-maize (MON810) in a long-term field trial on four South German sites	Journal für Verbraucherschutz und Lebensmittelsicherheit- Journal of Consumer Protection and Food Safety	2008	YES	YES	YES	YES
Gryspeirt A, Gregoire JC	Effects of two varieties of <i>Bacillus thuringiensis</i> maize on the biology of <i>Plodia interpunctella</i>	Toxins	2012	YES	YES	YES	YES
Guan Q, Wang X, Teng D, Yang Y, Tian F, Yin Q, Wang J	Construction of a standard reference plasmid for detecting GM cottonseed meal	Applied Biochemistry and Biotechnology	2011	NO	-	-	-
Guertler P, Brandl C, Meyer HHD, Tichopad A	Feeding genetically modified maize (MON810) to dairy cows: comparison of gene expression pattern of markers for apoptosis inflammation and Cell cycle	Journal für Verbraucherschutz und Lebensmittelsicherheit/Journal of Consumer Protection and Food Safety	2012	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Guertler P, Lutz B, Kuehn R, Meyer HHD, Einspanier R, Killermann B, Albrecht C	Fate of recombinant DNA and Cry1Ab protein after ingestion and dispersal of genetically modified maize in comparison to rapeseed by fallow deer (<i>Dama dama</i>)	European Journal of Wildlife Research	2008	YES	YES	YES	YES
Guertler P, Paul V, Albrecht C, Meyer HHD	Sensitive and highly specific quantitative real-time PCR and ELISA for recording a potential transfer of novel DNA and Cry1Ab protein from feed into bovine milk	Analytical and bioanalytical Chemistry	2009	YES	YES	YES	YES
Guertler P, Paul V, Albrecht C, Meyer HHD	Sensitive analytical methods for quantification of novel DNA and protein in bovine milk - first results from a long-term feeding study in dairy cows	Journal fuer verbraucherschutz und lebensmittelsicherheit/Journal of Consumer Protection and Food Safety	2008	YES	YES	YES	YES
Guertler P, Paul V, Steinke K, Wiedemann S, Preissinger W, Albrecht C, Spiekers H, Schwarz FJ, Meyer HHD	Long-term feeding of genetically modified corn (MON810) - Fate of cry1Ab DNA and recombinant protein during the metabolism of the dairy cow	Livestock Science	2010	YES	YES	YES	YES
Guimaraes V, Drumare MF, Lereclus D, Gohar M, Lamourette P, Nevers MC, Vaisanen-Tunkelrott ML, Bernard H, Guillon B, Creminon C, Wal JM, Adel-Patient K	In vitro digestion of Cry1Ab proteins and analysis of the impact on their immunoreactivity	Journal of Agricultural and Food Chemistry	2010	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Guo Z, Zhu YC, Huang F, Luttrell R, Leonard R	Microarray analysis of global gene regulation in the Cry1Ab-resistant and Cry1Ab-susceptible strains of <i>Diatraea saccharalis</i>	Pest Management Science	2012	YES	YES	YES	YES
Gurakan GC, Aydin G, Yilmaz R	Qualitative detection of GM maize (Bt 11) in food and feed sold commercially in Turkey by PCR based methods	Indian Journal of Biotechnology	2011	NO	-	-	-
Habustova O, Turanli F, Dolezal P, Ruzicka V, Spitzer L, Hussein HM	Environmental impact of Bt maize - three years of experience	Bulletin OILB/SROP	2006	YES	NO	-	-
Habustova O, Turanli F, Spitzer L, Ruzicka V, Dolezal P, Sehnal F	Communities of beetles and spiders in the stands of normal and genetically modified maize	Pestycydy	2005	YES	YES	YES	YES
Hammond BG, Dudek R, Lemen JK, Nemeth MA	Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn	Food and chemical Toxicology	2006	YES	YES	YES	YES
Hang TN, Jehle JA	Stability of Cry1Ab protein during long-term storage for standardization of insect bioassays	Environmental Biosafety Research	2009	YES	YES	YES	YES
Hardke JT, Leonard BR, Huang F, Jackson RE	Damage and survivorship of fall armyworm (Lepidoptera: Noctuidae) on transgenic field corn expressing <i>Bacillus thuringiensis</i> Cry proteins	Crop Protection	2011	YES	YES	YES	YES
Hari NS, Jawala J, Malhi NS	Resistance of Cry1Ab maize to spotted stemborer <i>Chilo partellus</i> (Lepidoptera: Crambidae) in India	International Journal of tropical Insect Science	2007	YES	YES	YES	NO

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Harwood JD, Obrycki JJ	The detection and decay of Cry1Ab Bt-endotoxins within non-target slugs <i>Deroceras reticulatum</i> (Mollusca: Pulmonata) following consumption of transgenic corn	BioControl Science and Technology	2006	YES	YES	YES	NO
Harwood JD, Samson R A, Obrycki JJ	Temporal detection of Cry1Ab-endotoxins in coccinellid predators from fields of <i>Bacillus thuringiensis</i> corn	Bulletin of Entomological Research	2007	YES	YES	YES	YES ³¹
Harwood JD, Samson RA, Obrycki JJ	No evidence for the uptake of Cry1Ab Bt-endotoxins by the generalist predator <i>Scarites subterraneus</i> (Coleoptera: Carabidae) in laboratory and field experiments	BioControl Science and Technology	2006	YES	YES	YES	YES ³²
Harwood JD, Wallin WG, Obrycki JJ	Uptake of Bt endotoxins by nontarget herbivores and higher order arthropod predators: molecular evidence from a transgenic corn agroecosystem	Molecular Ecology	2005	YES	YES	YES	YES
Haryu Y, Taguchi Y, Itakura E, Mikami O, Miura K, Saeki T, Nakajima Y	Longterm biosafety assessment of a genetically modified (GM) plant: the genetically modified (GM) insect-resistant Bt11 corn does not affect the performance of multi-generations or life span of mice	Open Plant Science Journal	2009	YES	YES	YES	NO

³¹ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

³² GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier/References

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
He K, Wang Z, Wen L, Bai S, Ma X, Yao Z	Determination of baseline susceptibility to Cry1Ab protein for Asian corn borer (Lep. Crambidae)	Journal of Applied Entomology	2005	YES	YES	YES	YES ³³
Heckmann LH, Griffiths BS, Caul S, Thompson J, Pusztai-Carey M, Moar WJ, Andersen MN, Krogh PH	Consequences for <i>Protaphorura armata</i> (Collembola: Onychiuridae) following exposure to genetically modified <i>Bacillus thuringiensis</i> (Bt) maize and non-Bt maize	Environmental pollution	2006	YES	YES	YES	YES ³⁴
Heide BR, Dromtorp SM, Rudi K, Heir E, Holck AL	Determination of eight genetically modified maize events by quantitative multiplex PCR and fluorescence capillary gel electrophoresis	European Food Research and Technology	2008	NO	-	-	-
Heide BR, Heir E, Holck A	Detection of eight GMO maize events by qualitative, multiplex PCR and fluorescence capillary gel electrophoresis	European Food Research and Technology	2008	NO	-	-	-
Hendriksma HP, Haertel S, Steffan-Dewenter I	Testing pollen of single and stacked insect-resistant Bt-maize on in vitro reared honey bee larvae	PLoS ONE	2011	YES	YES	YES	YES

³³ 2010 post-market environmental monitoring report on maize MON 810/References. The 2010 MON 810 report is publicly available on the webpage of the EC Directorate General for Health and Consumers, at http://ec.europa.eu/food/food/biotechnology/index_en.htm

³⁴ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Hernandez M, Rodriguez-Lazaro D, Zhang D, Esteve T, Pla M, Prat S	Interlaboratory transfer of a PCR multiplex method for simultaneous detection of four genetically modified maize lines: Bt11, MON810, T25, and GA21	Journal of Agricultural and Food Chemistry	2005	NO	-	-	-
Ho NH, Baisakh N, Oliva N, Datta K, Frutos R, Datta SK	Translational fusion hybrid Bt genes confer resistance against yellow stem borer in transgenic elite Vietnamese rice (<i>Oryza sativa</i> L.) cultivars	Crop Science	2006	NO	-	-	-
Holck AL, Dromtorp SM, Heir E	Quantitative, multiplex ligation-dependent probe amplification for the determination of eight genetically modified maize events	European Food Research and Technology	2009	NO	-	-	-
Hönemann L, Nentwig W	Are survival and reproduction of <i>Enchytraeus albidus</i> (Annelida: Enchytraeidae) at risk by feeding on Bt-maize litter?	European Journal of Soil Biology	2009	YES	YES	YES	YES
Hönemann L, Zurbrugg C, Nentwig W	Effects of Bt-corn decomposition on the composition of the soil meso- and macrofauna	Applied Soil Ecology	2008	YES	YES	YES	YES
Höss S, Arndt M, Baurngarte S, Tebbe CC, Nguyen HT, Jehle JA	Effects of transgenic corn and CryIAb protein on the nematode <i>Caenorhabditis elegans</i>	Ecotoxicology and Environmental Safety	2008	YES	YES	YES	YES ³⁵

³⁵ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Höss S, Nguyen HT, Menzel R, Pagel-Wieder S, Miethling-Graf R, Tebbe CC, Jehle JA, Traunspurger W	Assessing the risk posed to free-living soil nematodes by a genetically modified maize expressing the insecticidal Cry3Bb1 protein	Science of the Total Environment	2011	NO	-	-	-
Huang F, Andow DA, Buschman LL	Success of the high-dose/refuge resistance management strategy after 15 years of Bt crop use in North America	Entomologia experimentalis et applicata	2011	YES	YES	YES	YES
Huang F, Ghimire MN, Leonard BR, Daves C, Levy R, Baldwin J	Extended monitoring of resistance to <i>Bacillus thuringiensis</i> Cry1Ab maize in <i>Diatraea saccharalis</i> (Lepidoptera: Crambidae)	GM Crops & Food	2012	YES	YES	YES	YES
Huang F, Ghimire MN, Leonard BR, Wang J, Daves C, Levy R, Cook D, Head GP, Yang Y, Temple J, Ferguson R	F-2 screening for resistance to pyramided <i>Bacillus thuringiensis</i> maize in Louisiana and Mississippi populations of <i>Diatraea saccharalis</i> (Lepidoptera: Crambidae)	Pest Management Science	2011	NO	-	-	-
Huang F, Ghimire MN, Leonard BR, Zhu YC, Head GP	Susceptibility of field populations of sugarcane borer from non-Bt and Bt maize plants to five individual Cry toxins	Insect Science	2012	YES	YES	YES	YES
Huang F, Leonard BR, Cook DR, Lee DR, Andow DA, Baldwin JL, Tindall KV, Wu X	Frequency of alleles conferring resistance to <i>Bacillus thuringiensis</i> maize in Louisiana populations of the southwestern corn borer	Entomologia Experimentalis et Applicata	2007	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Huang F, Parker R, Leonard R, Yong Y, Liu J	Frequency of resistance alleles to <i>Bacillus thuringiensis</i> corn in Texas populations of the sugarcane borer <i>Diatraea saccharalis</i> (F.) (Lepidoptera: Crambidae)	Crop Protection	2009	YES	YES	YES	YES
Huang F, Rogers LB, Wu X	Resistance of sugarcane borer to <i>Bacillus thuringiensis</i> Cry1Ab toxin	Entomologia Experimentalis et Applicata	2007	YES	YES	YES	YES ³⁶
Huang FN, Leonard BR, Andow DA	F(2) screen for resistance to a <i>Bacillus thuringiensis</i> maize hybrid in the sugarcane borer (Lepidoptera: Crambidae)	Bulletin of Entomological Research	2007	YES	YES	YES	YES
Huang FN, Leonard BR, Andow DA	Sugarcane borer (Lepidoptera: Crambidae) resistance to transgenic <i>Bacillus thuringiensis</i> maize	Journal of Economic Entomology	2007	YES	YES	YES	YES
Huang FN, Leonard BR, Gable RH	Comparative susceptibility of European corn borer southwestern corn borer and sugarcane borer (Lepidoptera : Crambidae) to Cry1Ab protein in a commercial <i>Bacillus thuringiensis</i> corn hybrid	Journal of Economic Entomology	2006	YES	YES	YES	YES ³⁷
Huang FN, Leonard BR, Moore SH, Cook DR, Baldwin J, Tindall KV, Lee DR	Allele frequency of resistance to <i>Bacillus thuringiensis</i> Cry1Ab corn in Louisiana populations of sugarcane borer (Lepidoptera: Crambidae)	Journal of Economic Entomology	2008	YES	YES	YES	YES

³⁶ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 8.1a)/2008-09-30_add info ERA\References Table (Att 1)/CD Monitoring report MON 810 cult 2007

³⁷ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 8.1a)/2008-09-30_add info ERA\References Table (Att 1)/CD Monitoring report MON 810 cult 2007

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Hubert J, Kudlikova-Krizkova I, Stejskal V	Effect of MON 810 Bt transgenic maize diet on stored-product moths (Lepidoptera: Pyralidae)	Crop Protection	2008	YES	YES	YES	YES
Hubert J, Nesvorna M, Zemek R, Stara J, Stejskal V	Effects of metabolic inhibitors on activity of Cry1Ab toxin to inhibit growth of <i>Ephestia kuehniella</i> larvae	Pest Management Science	2008	YES	YES	YES	YES ³⁸
Hutchison WD, Storer NP	Expanded use of pyramided transgenic maize hybrids expressing novel <i>Bacillus thuringiensis</i> toxins in the southern US potential for areawide suppression of <i>Helicoverpa zea</i> (Lepidoptera Noctuidae) in the Mississippi delta	Southwestern Entomologist	2010	YES	YES	YES	YES
Icoz I, Saxena D, Andow D A, Zwahlen C, Stotzky G	Microbial populations and enzyme activities in soil in situ under transgenic corn expressing Cry proteins from <i>Bacillus thuringiensis</i>	Journal of Environmental Quality	2008	YES	YES	YES	YES
Icoz I, Saxena D, Andow DA, Zwahlen C, Stotzky G	Microbial populations and enzyme activities in soil in situ under transgenic corn expressing Cry proteins from <i>Bacillus thuringiensis</i>	Journal of Environmental Quality	2008	YES	YES	YES	YES
Jacobs JL, Diez-Gonzalez F, Stern MD, Phillips RL	Detection of transgenic maize Cry1Ab protein subjected to ruminal digestion	Journal of Animal and feed Sciences	2005	NO	-	-	-

³⁸ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2009-08-10_add info/CD Monitoring report MON 810 cult 2008

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Jafari M, Norouzi P, Malboobi MA, Ghareyazie B, Valizadeh M, Mohammadi SA, Mousavi M	Enhanced resistance to a lepidopteran pest in transgenic sugar beet plants expressing synthetic cry1Ab gene	Euphytica	2009	NO	-	-	-
Jalali SK, Lalitha Y, Kamath SP, Mohan KS, Head GP	Baseline sensitivity of lepidopteran corn pests in India to Cry1Ab insecticidal protein of <i>Bacillus thuringiensis</i>	Pest Management Science	2010	YES	YES	YES	YES
Jensen PD, Dively GP, Swan CM, Lamp WO	Exposure and nontarget effects of transgenic Bt corn Debris in streams	Environmental Entomology	2010	YES	YES	YES	YES
Jia X, Shuifang Z, Haizhen M, Wensheng H, Minyan Q, Yan H, Xuping F, Yao L	Event-specific detection of seven genetically modified soybean and maizes using multiplex-PCR coupled with oligonucleotide microarray	Journal of Agricultural and Food Chemistry	2007	NO	-	-	-
Kailasa SK, Seong HK	Ultra-fast simultaneous analysis of genetically modified organisms in maize by microchip electrophoresis with LIF detector	Electrophoresis	2007	NO	-	-	-
Kaiser-AR, Wagner W	Studies on the early detection of resistance development of the European Corn Borer (<i>Ostrinia nubilalis</i>) to the Bt corn toxin Cry1Ab and clearing up potential resistance mechanisms	Nachrichtenblatt des deutschen pflanzenschutzdienstes	2007	YES	YES	NO	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Kamath SP, Anuradha S, Vidya HS, Mohan KS, Dudin Y	Quantification of <i>Bacillus thuringiensis</i> Cry1Ab protein in tissues of YieldGard (R) (MON810) corn hybrids tested at multiple field locations in India	Crop Protection	2010	YES	YES	YES	YES
Kamota A, Muchaonyerwa P, Mkeni PNS	Effects of ensiling of <i>Bacillus thuringiensis</i> (Bt) maize (MON810) on degradation of the crystal 1Ab (Cry1Ab) protein and compositional quality of silage	African Journal of Biotechnology	2011	YES	YES	YES	YES
Keeping MG, Rutherford RS, Conlong DE	Bt-maize as a potential trap crop for management of <i>Eldana saccharina</i> Walker (Lep. Pyralidae) in sugarcane	Journal of Applied Entomology	2007	NO	-	-	-
Khan MS, Ali S, Iqbal J	Developmental and photosynthetic regulation of delta-endotoxin reveals that engineered sugarcane conferring resistance to 'dead heart' contains no toxins in cane juice	Molecular Biology Reports	2011	NO	-	-	-
Kim JH, Kim SY, Lee H, Kim YR, Kim HY	An event-specific DNA microarray to identify genetically modified organisms in processed foods	Journal of Agricultural and Food Chemistry	2010	NO	-	-	-
Kim JH, Seo YJ, Kim JY, Han YS, Lee KS, Kim SA, Kim HN, Ahn K, Lee SI, Kim HY	Allergenicity assessment of Cry proteins in insect-resistant genetically modified maize Bt11 MON810 MON863	Food Science and Biotechnology	2009	YES	YES	YES	YES
Kim JH, Song HG, Heo MS, Lee WY, Lee SH, Park SH, Park HK, Kim MC, Kim HY	Detection of eight different events of genetically modified maize by multiplex PCR method	Food Science and Biotechnology	2006	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Kim S, Kim C, Li W, Kim Tokyong, Li Y, Zaidi MA, Altosaar I	Inheritance and field performance of transgenic Korean Bt rice lines resistant to rice yellow stem borer	Euphytica	2008	NO	-	-	-
Kim YH, Hwang CE, Kim TS, Lee JH, Lee SH	Assessment of potential impacts due to unintentionally released Bt maize plants on non-target aphid <i>Rhopalosiphum padi</i> (Hemiptera: Aphididae)	Journal of Asia-Pacific Entomology	2012	YES	YES	YES	YES
Kim YH, Hwang CE, Kim TS, Lee JH, Lee SH	Risk assessment system establishment for evaluating the potential impacts of imported <i>Bacillus thuringiensis</i> maize on a non-target insect <i>Tenebrio molitor</i>	Journal of Asia-Pacific Entomology	2012	YES	YES	YES	YES
Knecht S, Nentwig W	Effect of Bt maize on the reproduction and development of saprophagous Diptera over multiple generations	Basic and Applied Ecology	2010	YES	YES	YES	YES
Kodama T, Kuribara H, Minegishi Y, Futo S, Watai M, Sawada C, Watanabe T, Akiyama H, Maitani T, Teshima R, Furui S, Hino A, Kitta K	Evaluation of modified PCR quantitation of genetically modified maize and soybean using reference molecules: interlaboratory study	Journal of AOAC International	2009	NO	-	-	-
Kramarz P, de Vaufléury A, Carey M	Studying the effect of exposure of the snail <i>Helix aspersa</i> to the purified Bt toxin Cry1Ab	Applied Soil Ecology	2007	YES	YES	YES	YES
Kramarz P, de Vaufléury A, Gimbert F, Cortet J, Tabone E, Andersen MN, Krogh PH	Effects of Bt-maize material on the life cycle of the land snail <i>Cantareus aspersus</i>	Applied Soil Ecology	2009	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Kruger M, Van Rensburg JBJ, Van den Berg J	Reproductive biology of Bt-resistant and susceptible field-collected larvae of the maize stem borer <i>Busseola fusca</i> (Lepidoptera: Noctuidae)	African Entomology	2012	YES	YES	YES	YES
Kruger M, Van Rensburg JBJ, Van den Berg J	Resistance to Bt maize in <i>Busseola fusca</i> (Lepidoptera: Noctuidae) From Vaalharts South Africa	Environmental Entomology	2011	YES	YES	YES	YES
Kumar KS, Kang SH	Ultra-fast simultaneous analysis of genetically modified organisms in maize by microchip electrophoresis with LIF detector	Electrophoresis	2007	NO	-	-	-
Kumar R	A real-time immuno-PCR assay for the detection of transgenic Cry1Ab protein	European Food Research and Technology	2012	NO	-	-	-
Kyrova V, Ostry V, Laichmannova L, Ruprich J	An occurrence of genetically modified foodstuffs on the Czech food market	Acta Alimentaria	2010	NO	-	-	-
La Paz JL, Esteve T, Pla M	Comparison of real-time PCR detection chemistries and cycling modes using MON810 event-specific assays as model	Journal of Agricultural and Food Chemistry	2007	NO	-	-	-
Lachance D, Hamel LP, Pelletier F, Valero J, Bernier-Cardou M, Chapman K, van Frankenhuyzen K, Seguin A	Expression of a <i>Bacillus thuringiensis</i> cry1Ab gene in transgenic white spruce and its efficacy against the spruce budworm (<i>Choristoneura fumiferana</i>)	Tree Genetics & Genomes	2007	NO	-	-	-
Lan QK, Wang Y, Zhao X, Chen R, Zhu Z, Li O, Yu J, Guo Y, Cheng Y	Special-base GMCs detection using multiple PCR and pyrosequencing	Journal of China Agricultural University	2012	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Lang A, Otto M	A synthesis of laboratory and field studies on the effects of transgenic <i>Bacillus thuringiensis</i> (Bt) maize on non-target Lepidoptera	Entomologia Experimentalis et Applicata	2010	YES	YES	YES	YES
Lang A, Vojtech E	The effects of pollen consumption of transgenic Bt maize on the common swallowtail <i>Papilio machaon</i> L. (Lepidoptera Papilionidae)	Basic and Applied Ecology	2006	YES	YES	YES	YES
Lawo NC, Romeis J	Assessing the utilization of a carbohydrate food source and the impact of insecticidal proteins on larvae of the green lacewing <i>Chrysoperla carnea</i>	Biological Control	2008	YES	YES	YES	YES ³⁹
Lehman RM, Osborne SL, Prischmann-Voldseth DA, Rosentrater KA	Insect-damaged corn stalks decompose at rates similar to Bt-protected non-damaged corn stalks	Plant and Soil	2010	YES	YES	YES	YES
Lehman RM, Osborne SL, Rosentrater KA	No differences in decomposition rates observed between <i>Bacillus thuringiensis</i> and non- <i>Bacillus thuringiensis</i> corn residue incubated in the field	Agronomy Journal	2008	YES	YES	YES	YES

³⁹ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Leimanis S, Hernandez M, Fernandez S, Boyer F, Burns M, Bruderer S, Glouden T, Harris N, Kaeppli O, Philipp P, Pla M, Puigdomenech P, Vaitilingom M, Bertheau Y, Remacle J	A microarray-based detection system for genetically modified (GM) food ingredients	Plant Molecular Biology	2006	NO	-	-	-
Leslie TW, Biddinger DJ, Mullin CA, Fleischer SJ	Carabidae population dynamics and temporal partitioning: response to coupled neonicotinoid-transgenic technologies in maize	Environmental Entomology	2009	YES	YES	YES	YES
Leslie TW, Biddinger DJ, Rohr JR, Fleischer SJ	Conventional and seed-based insect management strategies similarly influence non-target coleopteran communities in maize	Environmental Entomology	2010	NO	-	-	-
Lewandowski A, Gorecka J	Effect of transgenic maize MON 810 on selected non-target organisms: the bird cherry-oat aphid (<i>Rhopalosiphum padi</i> L.) and its predator - green lacewing (<i>Chrysoperla carnea</i> Steph)	Vegetable Crops Research Bulletin	2008	YES	YES	YES	YES
Li HR, Buschman LL, Huang FN, Zhu KY, Bonning B, Oppert B	DiPel-selected <i>Ostrinia nubilalis</i> larvae are not resistant to transgenic corn expressing <i>Bacillus thuringiensis</i> Cry1Ab	Journal of Economic Entomology	2007	YES	YES	YES	YES
Li HR, Buschman LL, Zhu KY, Huang FN, Oppert B	Resistance to <i>Bacillus thuringiensis</i> endotoxins in the European corn borer, <i>Ostrinia nubilalis</i>	Biopesticides International	2007	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Li L, Wang Z, He K, Bai S, Hua L	Effects of transgenic corn expressing <i>Bacillus thuringiensis</i> Cry1Ab toxin on population increase of <i>Rhopalosiphum maidis</i> Fitch	Chinese Journal of Applied Ecology	2007	YES	YES	NO	-
Li WD, Wu KM, Wang XQ, Wang GR, Guo YY	Impact of pollen grains from Bt transgenic corn on the growth and development of Chinese tussah silkworm <i>Antheraea pernyi</i> (Lepidoptera : Saturniidae)	Environmental Entomology	2005	YES	YES	YES	NO
Li Y, Meissle M, Romeis J	Use of maize pollen by adult <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae) and fate of Cry proteins in Bt-transgenic varieties	Journal of Insect Physiology	2010	YES	YES	YES	YES
Li Y, Meissle M, Romeis J	Consumption of Bt Maize pollen expressing Cry1Ab or Cry3Bb1 does not harm adult green lacewings <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae)	PLoS ONE	2008	YES	YES	YES	YES
Li Y, Romeis J	Bt maize expressing Cry3Bb1 does not harm the spider mite <i>Tetranychus urticae</i> or its ladybird beetle predator <i>Stethorus punctillum</i>	Biological Control	2010	NO	-	-	-
Lili C, Jinchao G, Qidi W, Guoyin K, Litao Y	Development of the visual loop-mediated isothermal amplification assays for seven genetically modified maize events and their application in practical samples analysis	Journal of Agricultural and Food Chemistry	2011	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Liu T, Guo W, Sun W, Sun Y	Biological characteristics of <i>Bacillus thuringiensis</i> strain Bt11 and identification of its cry-type genes	Frontiers of Agriculture in China	2009	NO	-	-	-
Liu W, Lu HH, Wu W, Wei QK, Chen YX, Thies Janice E	Transgenic Bt rice does not affect enzyme activities and microbial composition in the rhizosphere during crop development	Soil Biology & Biochemistry	2008	NO	-	-	-
Lopez MD, Sumerford DV, Lewis LC	Nosema pyrausta and Cry1Ab-incorporated diet led to decreased survival and developmental delays in European corn borer	Entomologia Experimentalis et Applicata	2010	YES	YES	YES	YES
Lu H, Wu W, Chen Y, Wang H, Devare M, Thies Janice E	Soil microbial community responses to Bt transgenic rice residue decomposition in a paddy field	Journal of Soils and sediments	2010	NO	-	-	-
Lu H, Wu W, Chen Y, Zhang X, Devare M, Thies JE	Decomposition of Bt transgenic rice residues and response of soil microbial community in rapeseed-rice cropping system	Plant and Soil	2010	NO	-	-	-
Lu X, Wu H, Wang M, Li B, Yang C, Sun H	Developing a method of oligonucleotide microarray for event specific detection of transgenic maize (<i>Zea mays</i>)	Acta Agronomica Sinica	2009	NO	-	-	-
Ludy C, Lang A	A 3-year field-scale monitoring of foliage-dwelling spiders (Araneae) in transgenic Bt maize fields and adjacent field margins	Biological Control	2006	YES	YES	YES	YES ⁴⁰

⁴⁰ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Ludy C, Lang A	Bt maize pollen exposure and impact on the garden spider <i>Araneus diadematus</i>	Entomologia Experimentalis et Applicata	2006	YES	YES	YES	YES ⁴¹
Lund MS, Sahana G, Andersson-Eklund L, Hastings N, Fernandez A, Schulman N, Thomsen B, Viitala S, Williams JL, Sabry A, Viinalass H, Vilkki J	Joint analysis of quantitative trait loci for clinical mastitis and somatic Cell score on five chromosomes in three Nordic dairy cattle breeds	Journal of Dairy Science	2007	NO	-	-	-
Lundgren JG, Wiedenmann RN	Tritrophic interactions among Bt (CryMbl) corn aphid prey and the predator <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae)	Environmental Entomology	2005	YES	YES	YES	YES
Lutz B, Albrecht C, Wiedemann S	Experiments to study the dispersal of transgenes through animals via plant dispersing agents after passage through the intestinal tract and via horizontal gene transfer	BFN - skripten (bundesamt für naturschutz)	2007	YES	NO	-	-
Lutz B, Wiedemann S, Albrecht C	Degradation of transgenic Cry1Ab DNA and protein in Bt-176 maize during the ensiling process	Journal of Animal Physiology and Animal Nutrition	2006	YES	YES	YES	YES
Lutz B, Wiedemann S, Einspanier R, Mayer J, Albrecht C	Degradation of Cry1Ab protein from genetically modified maize in the bovine gastrointestinal tract	Journal of Agricultural and Food Chemistry	2005	YES	YES	YES	YES

⁴¹ GM plant market registration application with reference EFSA-GMO-RX-MON 810(Art 20.1a) /Application/Non CI/Core dossier

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Macias-de la Cerda CG, Cantu-Iris M, Cruz-Requena M, Rodriguez-Herrera R, Gonzalez-Vazquez VM, Aguilar-Gonzalez CN, Loyola-Licea JC, Contreras-Esquivel JC	Transgenic sequences detected in corn soybean and cotton grains imported to Mexico	Indian Journal of Genetics and Plant breeding	2012	NO	-	-	-
Manetti C, Bianchetti C, Casciani L, Castro C, Di Cocco ME, Miccheli A, Motto M, Conti F	A metabonomic study of transgenic maize (<i>Zea mays</i>) seeds revealed variations in osmolytes and branched aminoacids	Journal of experimental Botany	2006	YES	YES	YES	YES
Mano J, Yanaka Y, Akiyama H, Teshima R, Furui S, Kitta K	Improvement of polymerase chain reaction-based Bt11 maize detection method by reduction of non-specific amplification	Food Hygiene and Safety Science	2010	NO	-	-	-
Mano J, Yanaka Y, Akiyama H, Teshima R, Furui S, Kitta K	Improvement of polymerase chain reaction-based Bt11 maize detection method by reduction of non-specific amplification	Shokuhin eiseigaku zasshi. Journal of the Food Hygienic Society of Japan	2010	NO	-	-	-
Marchetti E, Accinelli C, Talame V, Epifani R	Persistence of Cry toxins and cry genes from genetically modified plants in two agricultural soils	Agronomy for Sustainable Development	2007	YES	YES	YES	YES ⁴²
Marcos-Carcavilla A, Calvo JH, Gonzalez C, Moazami-Goudarzi K, Laurent P, Bertaud M, Hayes H, Alves MEF, Serrano M	Short communication. IL-1 family members as possible candidate genes affecting economically important traits in cattle	Spanish Journal of Agricultural Research	2007	NO	-	-	-

⁴² GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Margarit E, Reggiardo MI, Permingeat HR	Bt protein rhizosecreted from transgenic maize does not accumulate in soil	Electronic Journal of Biotechnology	2008	YES	YES	YES	NO
Marquez GC, Enns RM, Grosz MD, Alexander LJ, MacNeil MD	Quantitative trait loci with effects on feed efficiency traits in Hereford* composite double backcross populations	Animal Genetics	2009	NO	-	-	-
Mason CE, Sheldon JK, Pesek J, Bacon H, Gallusser R, Radke G, Slabaugh B	Assessment of <i>Chrysoperla plorabunda</i> longevity fecundity and egg viability when adults are fed transgenic Bt corn pollen	Journal of Agricultural and Urban Entomology	2008	YES	YES	YES	YES
Mattila HR, Sears MK, Duan JJ	Response of <i>Danaus plexippus</i> to pollen of two new Bt corn events via laboratory bioassay	Entomologia Experimentalis et Applicata	2005	YES	YES	YES	YES
Meise T, Langenbruch G A	Susceptibility of German populations of the Corn Borer <i>Ostrinia nubilalis</i> (Lepidoptera: Pyralidae) to a <i>Bacillus thuringiensis</i> endotoxin	Nachrichtenblatt des deutschen pflanzenschutzdienstes	2007	YES	YES	NO	-
Meissle M, Knecht S, Waldburger M, Romeis J	Sensitivity of the cereal leaf beetle <i>Oulema melanopus</i> (Coleoptera: Chrysomelidae) to Bt maize-expressed Cry3Bb1 and Cry1Ab	Arthropod-Plant Interactions	2012	YES	YES	YES	YES
Meissle M, Romeis J	Insecticidal activity of Cry3Bb1 expressed in Bt maize on larvae of the Colorado potato beetle <i>Leptinotarsa decemlineata</i>	Entomologia Experimentalis et Applicata	2009	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Meissle M, Romeis J	The web-building spider <i>Theridion impressum</i> (Araneae: Theridiidae) is not adversely affected by Bt maize resistant to corn rootworms	Plant Biotechnology Journal	2009	NO	-	-	-
Meissle M, Romeis J, Bigler F	Bt-Maize - A possible contribution to integrated production in Europe?	Agrarforschung schweiz	2012	YES	YES	NO	-
Meissle M, Romeis J, Bigler F	Bt maize and integrated pest management - a European perspective	Pest Management Science	2011	YES	YES	YES	YES
Meissle M, Vojtech E, Poppy GM	Effects of Bt maize-fed prey on the generalist predator <i>Poecilus cupreus</i> L. (Coleoptera: Carabidae)	Transgenic Research	2005	YES	YES	YES	YES
Mejia CRA, de Polania IZ	Expression of the Cry1AB toxin in transgenic corn Yieldgard (R) in the eastern plains of Colombia	Southwestern Entomologist	2012	YES	YES	NO	-
Michelotto MD, Finoto E L, Martins ALM, Duarte AP	Interaction between transgenics and insecticides in the control of key pests on off-season maize hybrids	Arquivos do instituto biologico (Sao Paulo)	2011	YES	YES	NO	-
Midega CAO, Khan ZR, Van den Berg J, Ogol CKPO, Pickett JA, Wadhams LJ	Maize stemborer predator activity under 'push-pull' system and Bt-maize: a potential component in managing Bt resistance	International Journal of Pest Management	2006	NO	-	-	-
Milcamps A, Rabe S, Cade R, De Framond AJ, Henriksson P, Kramer V, Lisboa D, Pastor-Benito S, Willits MG, Lawrence D, Van den Eede G	Validity assessment of the detection method of maize event Bt10 through investigation of its molecular structure	Journal of Agricultural and Food Chemistry	2009	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Mocali S, Castaldini M, Fabiani A, Marcucci A, Pagliai M, Benedetti A	Impact of different transgenic Bt corn varieties on microorganisms and soil quality	The Soils of tomorrow: Soils Changing in a Changing World	2008	YES	NO	-	-
Molteni L, Perucatti A, Iannuzzi A, Di Meo G P, De Lorenzi L, De Giovanni A, Incarnato D, Succi G, Cribiu E, Eggen A, Iannuzzi L	A new case of reciprocal translocation in a young bull: rcp(11;21)(q28;q12)	Cytogenetic and Genome Research	2007	NO	-	-	-
Monma K, Araki R, Sagi N, Satoh M, Ichikawa H, Satoh K, Tobe T, Kamata K, Hino A, Saito K	Detection of genetically modified organisms in foreign-made processed foods containing corn and potato	Shokuhin eiseigaku zasshi. Journal of the Food hygienic Society of Japan	2005	NO	-	-	-
Monma K, Moriuchi R, Sagi N, Ichikawa H, Satoh K, Tobe T, Kamata K	Investigation of false-positive reactions for CBH351 maize in screening PCR analysis	Shokuhin eiseigaku zasshi. Journal of the Food hygienic Society of Japan	2006	NO	-	-	-
Moro-Mendez J, Hayes J F	Associations between genetic polymorphisms of genes related to immune response and mastitis resistance in Canadian Holsteins	Proceedings of the 8th world congress on Genetics Applied to livestock production Belo Horizonte Minas Gerais Brazil 13-18 august 2006	2006	NO	-	-	-
Moser SE, Harwood JD, Obrycki JJ	Larval feeding on Bt hybrid and non-Bt corn seedlings by <i>Harmonia axyridis</i> (Coleoptera : Coccinellidae) and <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae)	Environmental Entomology	2008	YES	YES	YES	YES ⁴³

⁴³ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/PMEM reports/MON810 PMEM report 2008/References

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Mueting S, Lydy M	Environmental fate of the transgenic insecticidal protein Cry1Ab in water within a Bt maize agricultural ecosystem	Abstracts of papers of the American chemical Society	2011	YES	NO	-	-
Mugo S, Murenga MG, Karaya H, Tende R, Taracha C, Gichuki S, Ininda J, M'bijewe K, Chavangi A	Control of <i>Busseola fusca</i> and <i>Chilo partellus</i> stem borers by <i>Bacillus thuringiensis</i> (Bt)-delta-endotoxins from Cry1Ab gene event MON810 in greenhouse containment trials	African Journal of Biotechnology	2011	YES	YES	YES	YES
Mugo S, Mwimali M, Taracha CO, Songa JM, Gichuki ST, Tende R, Karaya H, Bergvinson DJ, Pellegrineschi A, Hoisington DA	Testing public Bt maize events for control of stem borers in the first confined field trials in Kenya	African Journal of Biotechnology	2011	NO	-	-	-
Mulder C, Wouterse M, Raubuch M, Roelofs W, Rutgers M	Can transgenic maize affect soil microbial communities?	PLoS Computational Biology	2006	YES	YES	YES	YES
Mulder C, Wouterse M, Rutgers M, Posthuma L	Transgenic maize containing the Cry1Ab protein ephemerally enhances soil microbial communities	Ambio	2007	YES	YES	YES	YES ⁴⁴
Muller AK, Schuppener M, Rauschen S	Assessing the impact of Cry1Ab expressing corn pollen on larvae of <i>Aglais urticae</i> in a laboratory bioassay.	IOBC/WPRS Bulletin	2012	YES	NO	-	-
Mullin CA, Saunders MC, Leslie TW, Biddinger DJ, Fleischer SJ	Toxic and behavioral effects to Carabidae of seed treatments used on Cry3Bb1- and Cry1Ab/c-protected corn	Environmental Entomology	2005	YES	YES	YES	YES

⁴⁴ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Murenga M, Danson J, Mugo S, Githiri SM, Wanjala B	Quantification of Bt delta-endotoxins in leaf tissues of tropical Bt maize populations	African Journal of Biotechnology	2012	NO	-	-	-
Murenga MG, Githiri SM, Mugo S, Olubayo FM	Levels of control of <i>Chilo partellus</i> stem borer in segregating tropical Bt maize populations in Kenya	African Journal of Biotechnology	2011	NO	-	-	-
Nadal A, Coll A, La Paz JL, Esteve T, Pla M	A new PCR-CGE (size and color) method for simultaneous detection of genetically modified maize events	Electrophoresis	2006	NO	-	-	-
Naef Andreas, Zesiger Thierry, Defago Genevieve	Impact of transgenic Bt maize residues on the mycotoxigenic plant pathogen <i>Fusarium graminearum</i> and the biocontrol agent <i>Trichoderma atroviride</i>	Journal of Environmental Quality	2006	YES	YES	YES	YES
Nakajima O, Teshima R, Takagi K, Okunuki H, Sawada J	ELISA method for monitoring human serum TgE specific for Cry1Ab introduced into genetically modified corn	Regulatory Toxicology and Pharmacology	2007	YES	YES	YES	NO
Nakasuji M, Koyama S, Takeuchi S, Mikami O, Tanimura N, Nakajima Y	The transfer of ingested plant and enterobacterial gene fragments into mice bodies and their shift to the livers of suckling mice through mother's milk	International Journal of Food engineering	2008	YES	YES	YES	NO
Nascimento VE, Von Pinho EVR, Von Pinho RG, do Nascimento AD	Detection limits of the strip test and PCR for genetically modified corn in Brazil	Genetics and molecular Research	2012	NO	-	-	-
Nguyen HT, Jehle JA	Quantitative analysis of the seasonal and tissue-specific expression of Cry1Ab in transgenic maize Mon810	Journal of Plant diseases and Protection	2007	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Nuessly GS, Scully BT, Hentz MG, Beiriger R, Snook ME, Widstrom NW	Resistance to <i>Spodoptera frugiperda</i> (Lepidoptera: Noctuidae) and <i>Euxesta stigmatias</i> (Diptera: Ulidiidae) in sweet corn derived from exogenous and endogenous genetic systems	Journal of Economic Entomology	2007	YES	YES	YES	NO
Obonyo DN, Lovei GL, Songa JM, Oyieke FA, Mugo SN, NyamasyoG HN	Developmental and mortality responses of <i>Chilo partellus</i> Swinhoe (Lepidoptera: Crambidae) and <i>Sesamia calamistis</i> Hampson (Lepidoptera: Noctuidae) following partial feeding on Bt-transgenic maize	Journal of Applied BioSciences(jabs)	2008	NO	-	-	-
Obonyo DN, Songa JM, Oyieke FA, Nyamasyo GHN, Mugo SN	Bt-transgenic maize does not deter oviposition by two important African cereal stem borers <i>Chilo partellus</i> Swinhoe (Lepidoptera: Crambidae) and <i>Sesamia calamistis</i> Hampson	Journal of Applied BioSciences	2008	NO	-	-	-
Obrist LB, Dutton A, Albajes R, Bigler F	Exposure of arthropod predators to Cry1Ab toxin in Bt maize fields	Ecological Entomology	2006	YES	YES	YES	YES
Obrist LB, Dutton A, Romeis J, Bigler F	Biological activity of Cry1Ab toxin expressed by Bt maize following ingestion by herbivorous arthropods and exposure of the predator <i>Chrysoperla carnea</i>	BioControl	2006	YES	YES	YES	YES
Obrist LB, Klein H, Dutton A, Bigler F	Assessing the effects of Bt maize on the predatory mite <i>Neoseiulus cucumeris</i>	Experimental and Applied Acarology	2006	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Obrist LB, Klein H, Dutton A, Bigler F	Effects of Bt maize on <i>Frankliniella tenuicornis</i> and exposure of thrips predators to prey-mediated Bt toxin	Entomologia Experimentalis et Applicata	2005	YES	YES	YES	YES
Oguchi T, Onishi M, Mano J, Akiyama H, Teshima R, Futo S, Furui S, Kittu K	Development of multiplex PCR method for simultaneous detection of four events of genetically modified maize: DAS-59122-7, MIR604, MON863 and MON88017	Food Hygiene and Safety Science	2010	NO	-	-	-
Oguchi T, Onishi M, Mano J, Akiyama H, Teshima R, Futo S, Furui S, Kittu K	Development of multiplex PCR method for simultaneous detection of four events of genetically modified maize: DAS-59122-7 MIR604 MON863 and MON88017	Shokuhin eiseigaku zasshi. Journal of the Food hygienic Society of Japan	2010	NO	-	-	-
Oliveira AP, Pampulha ME, Bennett JP	A two-year field study with transgenic <i>Bacillus thuringiensis</i> maize: effects on soil microorganisms	Science of the total Environment	2008	YES	YES	YES	YES
Onishi M, Matsuoka T, Kodama T, Kashiwaba K, Futo S, Akiyama H, Maitani T, Furui S, Oguchi T, Hino A	Development of a multiplex polymerase chain reaction method for simultaneous detection of eight events of genetically modified maize	Journal of Agricultural and Food Chemistry	2005	NO	-	-	-
Ortego F, Pons X, Albajes R, Castanera P	European commercial genetically modified plantings and field trials	Environmental impact of genetically modified Crops	2009	YES	NO	-	-
Papazova N, Zhang D, Gruden K, Vojvoda J, Yang L, Gasparic MB, Blejec A, Fouilloux S, De Loose M, Taverniers I	Evaluation of the reliability of maize reference assays for GMO quantification	Analytical and Bioanalytical Chemistry	2010	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Paul V, Albrecht C, Gurtler P, Steinke K, Preissinger W, Wiedemann S, Spiekers H, Schwarz FJ, Meyer HHD	Investigations on Cry1Ab protein transfer: analysis of blood plasma and milk of dairy cows fed genetically modified maize (MON810)	Proceedings of the Society of Nutrition Physiology	2008	YES	YES	YES	YES
Paul V, Guertler P, Wiedemann S, Meyer HHD	Degradation of Cry1Ab protein from genetically modified maize (MON810) in relation to total dietary feed proteins in dairy cow digestion	Transgenic Research	2010	YES	YES	YES	YES
Paul V, Steinke K, Meyer HHD	Development and validation of a sensitive enzyme immunoassay for surveillance of Cry1Ab toxin in bovine blood plasma of cows fed Bt-maize (MON810)	Analytica Chimica Acta	2008	YES	YES	YES	YES
Pavao AR, Ferreira Filho JB	Economic impact of Bt11 corn in Brazil: an inter-regional general equilibrium approach	Revista de Economia e Sociologia Rural	2011	NO	-	-	-
Peano C, Bordoni R, Gulli M, Mezzelani A, Samson MC, De Bellis G, Marmiroli N	Multiplex polymerase chain reaction and ligation detection reaction/universal array technology for the traceability of genetically modified organisms in foods	Analytical Biochemistry	2005	NO	-	-	-
Peano C, Lesignoli F, Gulli M, Corradini R, Samson MC, Marchelli R, Marmiroli N	Development of a peptide nucleic acid polymerase chain reaction clamping assay for semiquantitative evaluation of genetically modified organism content in food	Analytical Biochemistry	2005	NO	-	-	-
Pereira EJG, Lang BA, Storer NP, Siegfried BD	Selection for Cry1F resistance in the European corn borer and cross-resistance to other Cry toxins	Entomologia Experimentalis et Applicata	2008	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Perez-Hedo M, Albajes R, Eizaguirre M	Modification of hormonal balance in larvae of the Corn Borer <i>Sesamia nonagrioides</i> (Lepidoptera: Noctuidae) due to sublethal <i>Bacillus thuringiensis</i> protein ingestion	Journal of Economic Entomology	2011	YES	YES	YES	YES
Perez-Hedo M, Marques T, Lopez C, Albajes R, Eizaguirre M	Determination of the Cry1Ab toxin in <i>Helicoverpa armigera</i> larvae fed on a diet containing lyophilized Bt leaves	IOBC/WPRS Bulletin	2012	YES	NO	-	-
Perry JN, Devos Y, Arpaia S, Bartsch D, Ehlert C, Gathmann A, Hails RS, Hendriksen NB, Kiss J, Messean A, Mestdagh S, Neemann G, Nuti M, Sweet JB, Tebbe CC	Estimating the effects of Cry1F Bt-maize pollen on non-target Lepidoptera using a mathematical model of exposure	Journal of Applied Ecology	2012	YES	YES	YES	YES
Perry JN, Devos Y, Arpaia S, Bartsch D, Gathmann A, Hails RS, Kiss J, Lheureux K, Manachini B, Mestdagh S, Neemann G, Ortego F, Schiemann J, Sweet JB	The usefulness of a mathematical model of exposure for environmental risk assessment	Proceedings of the Royal Society B-Biological Sciences	2011	YES	YES	YES	YES
Perry JN, Devos Y, Arpaia S, Bartsch D, Gathmann A, Hails RS, Kiss J, Lheureux K, Manachini B, Mestdagh S, Neemann G, Ortego F, Schiemann J, Sweet JB	A mathematical model of exposure of nontarget Lepidoptera to Bt-maize pollen expressing Cry1Ab within Europe	Proceedings of the Royal Society B-Biological Sciences	2010	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Perucatti A, Genuardo V, Iannuzzi A, De Lorenzi L, Matassino D, Parma P, Di Berardino D, Iannuzzi L, Di Meo GP	A new and unusual reciprocal translocation in cattle: rcp(11;25)(q11;q14-21)	Cytogenetic and Genome Research	2011	NO	-	-	-
Peterson JA, Obrycki JJ, Harwood JD	Quantification of Bt-endotoxin exposure pathways in carabid food webs across multiple transgenic events	BioControl Science and Technology	2009	YES	YES	YES	YES
Peterson RKD, Meyer SJ, Wolf AT, Wolt JD, Davis PM	Genetically engineered plants endangered species and risk: A temporal and spatial exposure assessment for Karner blue butterfly larvae and Bt maize pollen	Risk analysis	2006	YES	YES	YES	YES ⁴⁵
Petit L, Baraige F, Bertheau Y, Brunshwig P, Diolez A, Duhem K, Duplan MN, Fach P, Kobilinsky A, Lamart S, Schattner A, Martin P	Detection of genetically modified corn (Bt176) in spiked cow blood samples by polymerase chain reaction and immunoassay methods	Journal of AOAC International	2005	NO	-	-	-
Piasecka-Jozwiak K, Kotyrba D, Zawadzka-Skonia J, Bucka J, Skwarczynski P	The detection and identification genetically modified maize in kernel and maize derived food products	Prace Instytutow i Laboratoriow Badawczych Przemyslu Spozywczego	2008	NO	-	-	-
Piccioni F, Capitani D, Zolla L, Mannina L	NMR metabolic profiling of transgenic Maize with the cry1A(b) gene	Journal of Agricultural and Food Chemistry	2009	YES	YES	YES	YES
Pilcher CD, Rice ME, Obrycki JJ	Impact of transgenic <i>Bacillus thuringiensis</i> corn and crop phenology on five nontarget arthropods	Environmental Entomology	2005	YES	YES	YES	YES ⁴⁶

⁴⁵ Peterson et al. (2006) referred to Perry et al. (2010)

⁴⁶ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Pinto A, Alfano F, Giordano A, Capuano F, Valentina T, Tantillo G	Quantitative real-time polymerase chain reaction for the presence of genetically-modified maize in breaded "ready-to-cook" food products	Food control	2008	NO	-	-	-
Pla M, La Paz JL, Penas G, Garcia N, Palau delmas M, Esteve T, Messeguer J, Mele E	Assessment of real-time PCR based methods for quantification of pollen-mediated gene flow from GM to conventional maize in a field study	Transgenic research	2006	NO	-	-	-
Poerschmann J, Gathmann A, Augustin J, Langer U, Gorecki T	Molecular composition of leaves and stems of genetically modified Bt and near-isogenic nonBt maize - Characterization of lignin patterns	Journal of Environmental Quality	2005	YES	YES	YES	YES
Pons X, Lumbierres B, Lopez C, Albajes R	Abundance of non-target pests in transgenic Bt-maize: a farm scale study	European Journal of Entomology	2005	YES	YES	YES	YES ⁴⁷
Prasifka JR, Hellmich R L, Sumerford DV, Siegfried BD	<i>Bacillus thuringiensis</i> resistance influences European Corn Borer (Lepidoptera: Crambidae) larval behavior after exposure to Cry1Ab	Journal of Economic Entomology	2009	YES	YES	YES	YES
Prasifka JR, Hellmich RL, Crespo ALB, Siegfried BD, Onstad DW	Video-tracking and on-plant tests show Cry1Ab resistance influences behavior and survival of neonate <i>Ostrinia nubilalis</i> following exposure to Bt maize	Journal of Insect behavior	2010	YES	YES	YES	YES

⁴⁷ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Prasifka JR, Sumerford D V, Hellmich RL, Lewis LC, Calvin DD	Sampling European corn borer (Lepidoptera : Crambidae) larvae from seed corn drying bins for Bt resistance monitoring	Southwestern Entomologist	2006	NO	-	-	-
Prasifka PL, Hellmich RL, Prasifka JR, Lewis LC	Effects of Cry1Ab-expressing corn anthers on the movement of monarch butterfly larvae	Environmental Entomology	2007	YES	YES	YES	YES
Priestley AL, Brownbridge M	Field trials to evaluate effects of Bt-transgenic silage corn expressing the Cry1Ab insecticidal toxin on non-target soil arthropods in northern New England USA	Transgenic Research	2009	YES	YES	YES	YES
Prutz G, Dettner K	Effects of transgenic <i>Bacillus thuringiensis</i> -maize on larval food consumption utilization and growth in the grass-moth species <i>Chilo partellus</i> under laboratory conditions (Lepidoptera : Crambidae)	Entomologia generalis	2005	NO	-	-	-
Qiu C, Sangha JS, Song F, Zhou Z, Yin A, Gu K, Tian D, Yang J, Yin Z	Production of marker-free transgenic rice expressing tissue-specific Bt gene	Plant Cell Reports	2010	NO	-	-	-
Ramirez-Romero R, Bernal JS, Chaufaux J, Kaiser L	Impact assessment of Bt-maize on a moth parasitoid <i>Cotesia marginiventris</i> (Hymenoptera: Braconidae) via host exposure to purified Cry1Ab protein or Bt-plants	Crop Protection	2007	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Ramirez-Romero R, Chaufaux J, Pham-Delegue MH	Effects of Cry1Ab protoxin deltamethrin and imidacloprid on the foraging activity and the learning performances of the honeybee <i>Apis mellifera</i> a comparative approach	Apidologie	2005	YES	YES	YES	YES
Ramirez-Romero R, Desneux N, Chaufaux J, Kaiser L	Bt-maize effects on biological parameters of the non-target aphid Sitobion avenae (Homoptera : Aphididae) and Cry1Ab toxin detection	Pesticide Biochemistry and Physiology	2008	YES	YES	YES	YES
Randhawa GJ, Singh M, Chhabra R, Sharma R	Qualitative and quantitative molecular testing methodologies and traceability systems for commercialised Bt cotton events and other Bt crops under field trials in India	Food Analytical Methods	2010	NO	-	-	-
Randhawa GJ, Singh M, Chhabra R, Sharma R	Validation of ST-LS1 as an endogenous reference gene for detection of amA1 and cry1Ab genes in genetically modified potatoes using multiplex and real time PCR	American Journal of potato Research	2009	NO	-	-	-
Rasco ET, Mangubat JR, Burgonio AB, Logrono M L, Villegas VN, Fernandez EC	Efficacy of insect-protected maize (Bt-11) against asiatic corn borer (<i>Ostrinia furnacalis</i> Guenee)	Philippine Journal of Crop Science	2008	YES	YES	YES	NO

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Rasco ET, Mangubat JR, Burgonio AB, Logrono ML, Villegas VN, Fernandez EC	Agronomic performance and Asiatic corn borer resistance of tropical converted transgenic corn hybrids containing the truncated Cry1A(b) gene (Bt-11) in Davao City, Philippines	Philippine Journal of Crop Science	2010	YES	YES	YES	YES ⁴⁸
Raubuch M, Roose K, Warnstorff K, Wichern F, Joergensen RG	Respiration pattern and microbial use of field-grown transgenic Bt-maize residues	Soil Biology & Biochemistry	2007	YES	YES	YES	YES
Rauschen S	A case of "pseudo science"? A study claiming effects of the Cry1Ab protein on larvae of the two-spotted ladybird is reminiscent of the case of the green lacewing	Transgenic Research	2010	YES	YES	YES	YES
Rauschen S, Eckert J, Schaarschmidt F, Schuphan I, Gathmann A	An evaluation of methods for assessing the impacts of Bt-maize MON810 cultivation and pyrethroid insecticide use on Auchenorrhyncha (planthoppers and leafhoppers)	Agricultural and forest Entomology	2008	YES	YES	YES	YES
Rauschen S, Nguyen HT, Schuphan I, Jehle JA, Eber S	Rapid degradation of the Cry3Bb1 protein from Diabrotica-resistant Bt-corn MON88017 during ensilation and fermentation in biogas production facilities	Journal of the Science of Food and agriculture	2008	NO	-	-	-

⁴⁸ GM plant market notification with reference C/F/96/05.10/2011.05.30_add data/Response to the EFSA request for additional information on the application C/F/96/05.10 of Bt11 maize cultivation/Appendix 2 - Literature Review: Bt11 maize studies on NTOs

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Rauschen S, Schaarschmidt F, Gathmann A	Occurrence and field densities of Coleoptera in the maize herb layer: implications for environmental risk assessment of genetically modified Bt-maize	Transgenic Research	2010	YES	YES	YES	YES
Rauschen S, Schultheis E, Pagel-Wieder S, Schuphan I, Eber S	Impact of Bt-corn MON88017 in comparison to three conventional lines on <i>Trigonotylus caelestialium</i> (Kirkaldy) (Heteroptera: Miridae) field densities	Transgenic Research	2009	NO	-	-	-
Rauschen S, Schuphan I	Fate of the Cry1Ab protein from Bt-maize MON810 silage in biogas production facilities	Journal of Agricultural and Food Chemistry	2006	YES	YES	YES	YES
Raybould A, Graser G, Hill K, Ward K	Ecological risk assessments for transgenic crops with combined insect-resistance traits: the example of Bt11 x MIR604 maize	Journal of Applied Entomology	2012	YES	YES	YES	YES
Raybould A, Higgins LS, Horak MJ, Layton RJ, Storer NP, De La Fuente JM, Herman RA	Assessing the ecological risks from the persistence and spread of feral populations of insect-resistant transgenic maize	Transgenic Research	2012	YES	YES	YES	YES
Raybould A, Stacey D, Vlachos D, Graser G, Li X, Joseph R	Non-target organism risk assessment of MIR604 maize expressing mCry3A for control of corn rootworm	Journal of Applied Entomology	2007	NO	-	-	-
Razze JM, Mason CE	Dispersal behavior of neonate European Corn Borer (Lepidoptera: Crambidae) on Bt corn	Journal of Economic Entomology	2012	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Razze JM, Mason CE, Pizzolato TD	Feeding behavior of neonate <i>Ostrinia nubilalis</i> (Lepidoptera: Crambidae) on Cry1Ab Bt corn: implications for resistance management	Journal of Economic Entomology	2011	YES	YES	YES	YES
Reay-Jones FPF, Wiatrak P	Evaluation of new transgenic corn hybrids producing multiple <i>Bacillus thuringiensis</i> toxins in South Carolina	Journal of Entomological Science	2011	YES	YES	YES	YES
Reay-Jones FPF, Wiatrak P, Greene JK	Evaluating the performance of transgenic corn producing <i>Bacillus thuringiensis</i> toxins in South Carolina	Journal of Agricultural and urban Entomology	2009	YES	YES	YES	YES
Ricroch A, Berge JB, Kuntz M	Is the German suspension of MON810 maize cultivation scientifically justified?	Transgenic Research	2010	NO	-	-	-
Rimachi Gamarra LF, Alcantara Delgado J, Aquino Villasante Y, Ortiz R	Detecting adventitious transgenic events in a maize center of diversity	Ejb electronic Journal of Biotechnology	2011	NO	-	-	-
Rizzi A, Brusetti L, Arioli S, Nielsen KM, Tamagnini I, Tamburini A, Sorlini C, Daffonchio D	Detection of feed-derived maize DNA in goat milk and evaluation of the potential of horizontal transfer to bacteria	European Food Research and Technology	2008	YES	YES	YES	YES ⁴⁹
Roda A, Mirasoli M, Guardigli M, Michelini E, Simoni P, Magliulo M	Development and validation of a sensitive and fast chemiluminescent enzyme immunoassay for the detection of genetically modified maize	Analytical and bioanalytical Chemistry	2006	NO	-	-	-

⁴⁹ Rizzi et al. (2008) referred to in EFSA (2009d)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Rodrigo-Simon A, de Maagd RA, Avilla C, Bakker PL, Molthoff J, Gonzalez-Zamora JE, Ferre J	Lack of detrimental effects of <i>Bacillus thuringiensis</i> cry toxins on the insect predator <i>Chrysoperla carnea</i> : a toxicological histopathological and biochemical analysis	Applied and Environmental Microbiology	2006	YES	YES	YES	YES
Rodriguez-Nogales JM, Cifuentes A, Garcia MC, Marina ML	Improved methodology for the characterisation of transgenic Bt-11 maize cultivars using RP-HPLC profiles of albumin, globulin, prolamin, and glutelin protein fractions and chemometric analysis	Food Chemistry	2010	NO	-	-	-
Romeis J, Alvarez-Alfageme F, Bigler F	Putative effects of Cry1Ab to larvae of <i>Adalia bipunctata</i> -reply to Hilbeck et al. (2012)	Environmental Sciences europe	2012	YES	YES	YES	YES
Romeis J, Meissle M, Alvarez-Alfageme F	Proceedings of the IOBC/WPRS Working Group "GMOs in Integrated Plant Production" Ceske Budejovice Czech Republic 22-25 June 2011	IOBC/WPRS Bulletin	2012	YES	NO	-	-
Rose R, Dively GP	Effects of insecticide-treated and lepidopteran-active Bt transgenic sweet corn on the abundance and diversity of arthropods	Environmental Entomology	2007	YES	YES	YES	YES ⁵⁰
Rose R, Dively GP, Pettis J	Effects of Bt corn pollen on honey bees: emphasis on protocol development	Apidologie	2007	YES	YES	YES	YES ⁵¹

⁵⁰ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

⁵¹ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Rosi-Marshall EJ, Tank J L, Royer TV, Whiles MR, Evans-White M, Chambers C, Griffiths N A, Pokelsek J, Stephen ML	Toxins in transgenic crop byproducts may affect headwater stream ecosystems	Proceedings of the national academy of Sciences of the united states of america	2007	YES	YES	YES	YES ⁵²
Ryffel Gerhart U	Dismay with GM maize A science-based solution to public resistance against genetically modified crops that could be compatible with organic farming	Embo Reports	2011	NO	-	-	-
Saeglitz C, Bartsch D, Eber S, Gathmann A, Priesnitz KU, Schuphan I	Monitoring the Cry1Ab susceptibility of European corn borer in Germany	Journal of Economic Entomology	2006	YES	YES	YES	YES
Salvi S, D'Orso F, Morelli G	Detection and quantification of genetically modified organisms using very short, locked nucleic acid TaqMan probes	Journal of Agricultural and Food Chemistry	2008	NO	-	-	-
Sanchez L, Gonzalez R, Crego AL, Cifuentes A	A simple capillary gel electrophoresis approach for efficient and reproducible DNA separations. Analysis of genetically modified soy and maize	Journal of Separation Science	2007	NO	-	-	-
Sanchis Vincent, Bourguet Denis	Bacillus thuringiensis. Biopesticides and transgenic plants	Biofutur	2007	YES	YES	NO	-

⁵² GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Sanders CJ, Pell JK, Poppy GM, Raybould A, Garcia-Alonso M, Schuler TH	Host-plant mediated effects of transgenic maize on the insect parasitoid <i>Campoletis sonorensis</i> (Hymenoptera: Ichneumonidae)	Biological Control	2007	YES	YES	YES	YES ⁵³
Sanvido O, Romeis J, Bigler F	Environmental change challenges decision-making during post-market environmental monitoring of transgenic crops	Transgenic Research	2011	YES	YES	YES	YES
Sanvido O, Romeis J, Bigler F	An approach for post-market monitoring of potential environmental effects of Bt-maize expressing Cry1Ab on natural enemies	Journal of Applied Entomology	2009	YES	YES	YES	YES
Sanvido O, Romeis J, Bigler F	Ecological impacts of genetically modified crops: ten years of field research and commercial cultivation	Green gene Technology: Research in an area of social conflict	2007	YES	YES	YES	YES
Sass M, Schorling M, Gossmann M, Buettner C	Varieties and infestation of <i>Fusarium</i> spp. in Bt maize and conventional maize in the European corn borer infested area Oderbruch region (Germany)	Gesunde pflanzen	2007	YES	YES	NO	-
Scholdberg TA, Norden TD, Nelson DD, Jenkins GR	Evaluating precision and accuracy when quantifying different endogenous control reference genes in maize using real-time PCR	Journal of Agricultural and Food Chemistry	2009	NO	-	-	-

⁵³ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Schopen GCB, Koks PD, van Arendonk JAM, Bovenhuis H, Visker MH	Whole Genome scan to detect quantitative trait loci for bovine milk protein composition	Animal Genetics	2009	NO	-	-	-
Schrader S, Muenchenberg T, Baumgarte S, Tebbe CC	Earthworms of different functional groups affect the fate of the Bt-toxin Cry1Ab from transgenic maize in soil	European Journal of Soil Biology	2008	YES	YES	YES	YES
Schulman NF, Viitala SM, Vilkki JH	Quantitative trait loci for udder conformation and other udder traits in Finnish Ayrshire cattle	Agricultural and Food Science	2007	NO	-	-	-
Schuppener M, Muehlhause J, Mueller AK, Rauschen S	Environmental risk assessment for the small tortoiseshell <i>Aglais urticae</i> and a stacked Bt-maize with combined resistances against Lepidoptera and Chrysomelidae in central European agrarian landscapes	Molecular Ecology	2012	NO	-	-	-
Sharma P, Nain V, Lakhanpaul S, Kumar PA	Binding of <i>Bacillus thuringiensis</i> Cry1A toxins with brush border membrane vesicles of maize stem borer (<i>Chilo partellus</i> Swinhoe)	Journal of Invertebrate Pathology	2011	NO	-	-	-
Sharma P, Nain V, Lakhanpaul S, Kumar PA	Synergistic activity between <i>Bacillus thuringiensis</i> Cry1Ab and Cry1Ac toxins against maize stem borer (<i>Chilo partellus</i> Swinhoe)	Letters in Applied Microbiology	2010	NO	-	-	-
Sharma R, Damgaard D, Alexander TW, Dugan MER, Aalhus JL, Stanford K, McAllister TA	Detection of transgenic and endogenous plant DNA in digesta and tissues of sheep and pigs fed Roundup Ready canola meal	Journal of Agricultural and Food Chemistry	2006	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Shelton AM, Naranjo SE, Romeis J, Hellmich RL	Errors in Logic and Statistics Plague a Meta-Analysis (response to Andow and Lovei 2012)	Environmental Entomology	2012	YES	YES	YES	YES
Shimada N Murata H, Mikami O, Yoshioka M, Guruge KS, Yamanaka N, Nakajima Y, Miyazaki S	Effects of feeding calves genetically modified corn Bt11: A clinico-biochemical study	Journal of Veterinary Medical Science	2006	YES	YES	YES	YES ⁵⁴
Shimada N, Murata H, Miyazaki S	Safety evaluation of Bt Plants	Jarq-Japan Agricultural Research Quarterly	2008	NO	-	-	-
Shirai Y, Takahashi M	Effects of transgenic Bt corn pollen on a non-target lycaenid butterfly <i>Pseudaugeria maha</i>	Applied Entomology and Zoology	2005	YES	YES	YES	YES ⁵⁵
Shrestha HK, Hwu KK, Wang SJ, Liu LF, Chang MC	Simultaneous detection of eight genetically modified maize lines using a combination of event- and construct-specific multiplex-PCR technique	Journal of Agricultural and Food Chemistry	2008	NO	-	-	-
Shu Y, Ma H, Du Y, Li Z, Feng Y, Wang J	The presence of <i>Bacillus thuringiensis</i> (Bt) protein in earthworms <i>Eisenia fetida</i> has no deleterious effects on their growth and reproduction	Chemosphere	2011	YES	YES	YES	YES
Shuang W, Zhen C, Jun M, Wei-Bin B, Xi-Yang W	Multiplex tandem PCR assays for the detection of genetically modified organisms	Scientia Agricultura Sinica	2012	NO	-	-	-
Sieradzki Z, Kwiatek K	Validation of real-time PCR methods for the quantification of genetically-modified maize and soybean	Bulletin of the Veterinary Institute in Pulawy	2009	NO	-	-	-

⁵⁴ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/ 2008-12-05_add info under RA/References

⁵⁵ GM plant market notification with reference C/F/96/05.10/2011.05.30_add data/Response to the EFSA request for additional information on the application C/F/96/05.10 of Bt11 maize cultivation/Appendix 2 - Literature Review: Bt11 maize studies on NTOs

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Sieradzki Z, Mazur M, Kwiatek K	Occurrence of genetically modified crops in animal feedingstuffs in Poland	Krmiva	2010	NO	-	-	-
Sieradzki Z, Mazur M, Kwiatek K	Validation of procedures based on PCR reactions for detection and identification of genetically modified maize and soybean	Bulletin of the Veterinary Institute in Pulawy	2008	NO	-	-	-
Silva RR da, Theodoro G de F, Liborio CB de, Pessoa LGA	Effect of crop density of two genotypes of maize in the severity of gray leaf spot and yield in the second season crop	Semina: ciencias agrarias (londrina)	2012	YES	YES	NO	-
Singh R, Channappa RK, Deeba F, Nagaraj NJ, Sukavaneaswaran MK, Manjunath TM	Tolerance of Bt corn (MON 810) to maize stem borer <i>Chilo partellus</i> (Lepidoptera: Pyralidae)	Plant Cell Reports	2005	YES	YES	YES	YES
Soberon M, Gill SS, Bravo A	Signaling versus punching hole: How do <i>Bacillus thuringiensis</i> toxins kill insect midgut cells?	Cellular and molecular life Sciences	2009	YES	YES	YES	YES
Steinke K, Guertler P, Paul V, Wiedemann S, Ettle T, Albrecht C, Meyer HHD, Spiekers H, Schwarz FJ	Effects of long-term feeding of genetically modified corn (event MON810) on the performance of lactating dairy cows	Journal of Animal Physiology and Animal Nutrition	2010	YES	YES	YES	YES
Steinke K, Spiekers H	Foreign genes in animal feeds. Feeding trials using genetically modified maize	Neue landwirtschaft	2009	NO	-	-	-
Stephens EJ, Losey JE, Allee LL, DiTommaso A, Bodner C, Breyre A	The impact of Cry3Bb Bt-maize on two guilds of beneficial beetles	Agriculture Ecosystems & Environment	2012	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Stodola TJ, Andow DA, Hyden AR, Hinton JL, Roark JJ, Buschman LL, Porter P, Cronholm GB	Frequency of resistance to <i>Bacillus thuringiensis</i> toxin Cry1Ab in southern United States corn belt population of European corn borer (Lepidoptera: Crambidae)	Journal of Economic Entomology	2006	YES	YES	YES	YES
Storer NP, Babcock JM, Schlenz M, Meade T, Thompson GD, Bing JW, Huckaba RM	Discovery and characterization of field resistance to Bt maize: <i>Spodoptera frugiperda</i> (Lepidoptera: Noctuidae) in Puerto Rico	Journal of Economic Entomology	2010	NO	-	-	-
Sulan B, Jie Z, Shucheng L, Haodong C, Terzaghi W, Xin Z, Xiurong C, Jin T, Hongxia L, Wensheng H, Ying C, Yaochuan Z	Detection of six genetically modified maize lines using optical thin-film biosensor chips	Journal of Agricultural and Food Chemistry	2010	NO	-	-	-
Szekacs A, Darvas B	Environmental assessment of MON 810 maize in the pannonian biogeographical region	Acta phytopathologica et Entomologica hungarica	2012	YES	YES	YES	YES
Szekacs A, Lauber E, Juracsek J, Darvas B	Cry1ab toxin production of MON 810 transgenic maize	Environmental Toxicology and Chemistry	2010	YES	YES	YES	YES
Szekacs A, Lauber E, Takacs E, Darvas B	Detection of Cry1Ab toxin in the leaves of MON 810 transgenic maize	Analytical and bioanalytical Chemistry	2010	YES	YES	YES	YES
Szekacs A, Weiss G, Quist D, Takacs E, Darvas B, Meier M, Swain T, Hilbeck A	Inter-laboratory comparison of Cry1Ab toxin quantification in MON 810 maize by enzyme-immunoassay	Food and Agricultural Immunology	2012	YES	YES	YES	YES
Szekeres D, Kadar F, Kiss J	Ground beetle (Coleoptera Carabidae) assemblages in Bt-(Cry1Ab MON 810) and isogenic maize plots in Hungary	Novenyvedelem	2006	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Tabashnik BE, Carriere Y	Insect resistance to genetically modified crops	Environmental impact of genetically modified Crops	2009	YES	NO	-	-
Tabashnik BE, Van Rensburg JBJ, Carriere Y	Field-evolved insect resistance to Bt crops: definition theory and data	Journal of Economic Entomology	2009	YES	YES	YES	YES
Takacs E, Darvas B, Szekacs A	Analytical difficulties and certain biological aspects of Cry1Ab toxin determination in MON 810 genetically modified maize	Acta phytopathologica et Entomologica hungarica	2012	NO	-	-	-
Tamez-Guerra P	A review of US and Mexican cooperation to develop insect resistance management and monitoring methods for surveying transgenic crops expressing <i>Bacillus thuringiensis</i> proteins 2003 to 2010	Southwestern Entomologist	2010	YES	YES	YES	YES
Tan F, Wang J, Chen Z, Feng Y, Chi G, Rehman SU	Assessment of the arbuscular mycorrhizal fungal community in roots and rhizosphere soils of Bt corn and their non-Bt isolines	Soil Biology & Biochemistry	2011	YES	YES	YES	YES
Tan F, Wang J, Feng Y, Chi G, Kong H, Qiu H, Wei S	Bt corn plants and their straw have no apparent impact on soil microbial communities	Plant and Soil	2010	YES	YES	YES	YES
Tan SY, Cayabyab BF, Alcantara EP, Ibrahim YB, Huang F, Blankenship EE, Siegfried BD	Comparative susceptibility of <i>Ostrinia furnacalis</i> <i>Ostrinia nubilalis</i> and <i>Diatraea saccharalis</i> (Lepidoptera: Crambidae) to <i>Bacillus thuringiensis</i> Cry1 toxins	Crop Protection	2011	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Tank JL, Rosi-Marshall EJ, Royer TV, Whiles MR, Griffiths NA, Frauendorf TC, Treering DJ	Occurrence of maize detritus and a transgenic insecticidal protein (Cry1Ab) within the stream network of an agricultural landscape	Proceedings of the national academy of Sciences of the united states of america	2010	YES	YES	YES	YES
Tarkalson DD, Kachman SD, Knops Johannes MN, Thies JE, Wortmann CS	Decomposition of Bt and non-Bt corn hybrid residues in the field	Nutrient cycling in agroecosystems	2008	YES	YES	YES	YES
Taverniers I, Windels P, Vaitilingom M, Milcamps A, Van Bockstaele E, Van den Eede G, De Loose M	Event-specific plasmid standards and real-time PCR methods for transgenic Bt11, Bt176, and GA21 maize and transgenic GT73 canola	Journal of Agricultural and Food Chemistry	2005	NO	-	-	-
Tende RM, Mugo S, Nderitu JH, Olubayo FIM, Songa JM, Bergvinson DJ	Evaluation of Chilo partellus and Busseola fusca susceptibility to delta-endotoxins in Bt maize	Crop Protection	2010	YES	YES	YES	YES
Tian JC, Liu ZC, Chen M, Chen Y, Chen XX, Peng YF, Hu C, Ye GY	Laboratory and field assessments of prey-mediated effects of transgenic Bt Rice on <i>Ummeliata insecticeps</i> (Araneida: Linyphiidae)	Environmental Entomology	2010	NO	-	-	-
Tian Y, Zhang YJ, Wu KM, Zhao KJ, Peng YF, Guo YY	Effects of transgenic Bt-cry1Ab corn pollen on the growth development and enzymes activity in <i>Apis mellifera</i> (L.) (Hymenoptera: Apidae)	Journal of Agricultural Biotechnology	2006	YES	YES	NO	-
Tinland B, Delzenne P, Pleysier A	Implementation of a post-market monitoring for insect-protected maize MON 810 in the EU	Journal fur verbraucherschutz und lebensmittelsicherheit- Journal of Consumer Protection and Food Safety	2007	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Tiwari S, Youngman RR, Laub CA, Brewster CC, Jordan TA, Teutsch C	European Corn Borer (Lepidoptera: Crambidae) infestation level and plant growth stage on whole-plant corn yield grown for silage in Virginia	Journal of Economic Entomology	2009	YES	YES	YES	YES
Toschki A, Hothorn LA, Ross-Nickoll M	Effects of cultivation of genetically modified Bt maize on epigeic arthropods (Araneae; Carabidae)	Environmental Entomology	2007	YES	YES	YES	YES
Tounou AK, Gounou S, Borgemeister C, Goumedzoe YMD, Schulthess F	Susceptibility of <i>Eldana saccharina</i> (Lepidoptera: Pyralidae) <i>Busseola fusca</i> and <i>Sesamia calamistis</i> (Lepidoptera: Noctuidae) to <i>Bacillus thuringiensis</i> Cry toxins and potential side effects on the larval parasitoid <i>Cotesia sesamiae</i> (Hymenoptera: Braconidae)	BioControl Science and Technology	2005	YES	YES	YES	YES ⁵⁶
Tremblay GF, Laberge S, Castonguay Y, Chiquette J, Ouellet DR, Delaney S, Petit HV, Michaud R	Outcome of Bt transgenes and protein in corn silage, processed grains, and rumen content	Canadian Journal of Animal Science	2008	YES	YES	YES	NO
Turlings TCJ, Jeanbourquin PM, Held M, Degen T	Evaluating the induced-odour emission of a Bt maize and its attractiveness to parasitic wasps	Transgenic Research	2005	YES	YES	YES	NO
Turrini A, Sbrana C, Giovannetti M	Experimental systems to monitor the impact of transgenic corn on keystone soil microorganisms	Proceedings abstract	2008	YES	NO	-	-

⁵⁶ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 8.1a)/2008-09-30_add info ERA\References Table (Att 1)/CD Monitoring report MON 810 cult 2007

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Twardowski JP, Beres P, Hurej M, Klukowski Z	Ground beetles (Col. Carabidae) in Bt-maize - preliminary results from the first large scale field experiment in Poland.	IOBC/WPRS Bulletin	2010	YES	NO	-	-
Valicente FH, Lana UG de P	Molecular characterization of the <i>Bacillus thuringiensis</i> (Berliner) strains 344 and 1644 efficient against fall armyworm <i>Spodoptera frugiperda</i> (J. E. Smith)	Revista brasileira de milho e sorgo	2008	NO	-	-	-
van Wyk A, Berg J, Rensburg JBJ	Comparative efficacy of Bt maize events MON810 and Bt11 against <i>Sesamia calamistis</i> (Lepidoptera: Noctuidae) in South Africa.	Crop Protection	2009	YES	YES	YES	YES
Verbruggen E, Kuramae EE, Hillekens R, de Hollander M, Kiers ET, Roling WFM, Kowalchuk GA, van der Heijden MGA	Testing potential effects of maize expressing the <i>Bacillus thuringiensis</i> Cry1Ab endotoxin (Bt Maize) on mycorrhizal fungal communities via DNA- and RNA-based pyrosequencing and molecular fingerprinting	Applied and Environmental Microbiology	2012	YES	YES	YES	YES
Vercesi ML, Krogh PH, Holmstrup M	Can <i>Bacillus thuringiensis</i> (Bt) corn residues and Bt-corn plants affect life-history traits in the earthworm <i>Aporrectodea caliginosa</i> ?	Applied Soil Ecology	2006	YES	YES	YES	YES ⁵⁷
Viktorov AG	Transfer of Bt corn byproducts from terrestrial to stream ecosystems	Russian Journal of Plant Physiology	2011	YES	YES	YES	YES

⁵⁷ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/Application/Non CI/Core dossier

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Villanyi I, Fuzy A, Biro B	Non-target microorganisms affected in the rhizosphere of the transgenic Bt corn	Cereal Research communications	2006	YES	NO	-	-
Volpe G, Ammid NH, Moscone D, Occhigrossi L, Palleschi G	Development of an immunomagnetic electrochemical sensor for detection of BT-CRY1AB/CRY1AC proteins in genetically modified corn samples	Analytical Letters	2006	NO	-	-	-
Walsh MC, Buzoianu SG, Gardiner GE, Rea MC, Gelencser E, Janosi A, Epstein MM, Ross RP, Lawlor PG	Fate of transgenic DNA from orally administered Bt MON810 maize and effects on immune response and growth in pigs	PloS ONE	2011	YES	YES	YES	YES
Walsh MC, Buzoianu SG, Gardiner GE, Rea MC, Ross RP, Cassidy JP, Lawlor PG	Effects of short-term feeding of Bt MON810 maize on growth performance organ morphology and function in pigs	British Journal of Nutrition	2012	YES	YES	YES	YES
Walsh MC, Buzoianu SG, Rea MC, O'Donovan O, Gelencser E, Ujhelyi G, Ross RP, Gardiner GE, Lawlor PG	Effects of feeding Bt MON810 maize to pigs for 110 days on peripheral immune response and digestive fate of the cry1Ab gene and truncated Bt toxin	PLoS ONE	2012	YES	YES	YES	YES
Wang DY, Wang ZY, He KL, Cong B	Feeding behavior of <i>Ostrinia furnacalis</i> larvae on transgenic Bt corn expressing Cry1Ab toxin	Chinese Bulletin of Entomology	2005	YES	YES	NO	-
Wang S, Guo AY, Zheng WJ, Zhang Y, Qiao H, Kennedy IR	Development of ELISA for the determination of transgenic Bt-cottons using antibodies against Cry1Ac protein from <i>Bacillus thuringiensis</i> HD-73	Engineering in life Sciences	2007	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Wang Y, Li Y, Romeis J, Chen X, Zhang J, Chen H, Peng Y	Consumption of Bt rice pollen expressing Cry2Aa does not cause adverse effects on adult <i>Chrysoperla sinica</i> Tjeder (Neuroptera: Chrysopidae)	Biological Control	2012	NO	-	-	-
Wang Y, Xu W, Zhao We, Hao J, Luo Y, Tang X, Zhang Y, Huang K	Comparative analysis of the proteomic and nutritional composition of transgenic rice seeds with Cry1ab/ac genes and their non-transgenic counterparts	Journal of cereal Science	2012	NO	-	-	-
Wang YH, Chen XQ, Xue J, Yang FP, Li XL, Zhang XiaoD	Expression of Cry1Ab/1Ac gene in transgenic maize	Molecular Plant breeding	2010	YES	YES	NO	-
Wang ZY, Wang DY, He KL, Bai SX, Cong B	Evaluation the control effects of the transgenic <i>Bacillus thuringiensis</i> corn expressing Cry1Ab protein on the larvae of <i>Mythimna separata</i> (Walker) in laboratory	Acta Phytophylacica Dinica	2005	YES	YES	NO	-
Wang ZY, Wu Y, He KL, Bai SX	Effects of transgenic Bt maize pollen on longevity and fecundity of <i>Trichogramma ostriniae</i> in laboratory conditions	Bulletin of insectology	2007	YES	YES	YES	YES ⁵⁸
Weber M, Nentwig W	Impact of Bt corn on the diplopod <i>Allajulus latestriatus</i>	Pedobiologia	2006	YES	YES	YES	YES

⁵⁸ GM plant market registration application with reference EFSA-GMO-RX-MON 810 (Art 20.1a)/2008-06-09_add info ERA CA\References Table (Att 1)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Wen LP, He KL, Wang ZY, Zhou DR, Bai SX	Susceptibility of <i>Ostrinia furnacalis</i> to <i>Bacillus thuringiensis</i> and Bt corn under long-term laboratory selection	Agricultural Sciences in china	2005	YES	YES	YES	YES ⁵⁹
White DM, Blair CD, Beaty BJ	Molecular epidemiology of Bluetongue virus in northern Colorado	Virus Research	2006	NO	-	-	-
Wiedemann S, Lutz B, Albrecht C, Kuehn R, Killermann B, Einspanier R, Meyer HHD	Fate of genetically modified maize and conventional rapeseed and endozoochory in wild boar (<i>Sus scrofa</i>)	Mammalian Biology	2009	NO	-	-	-
Wiedemann S, Lutz B, Kurtz H, Schwarz FJ, Albrecht C	In situ studies on the time-dependent degradation of recombinant corn DNA and protein in the bovine rumen	Journal of Animal Science	2006	YES	YES	YES	YES
Wilhelm R, Sanvido O, Castanera P, Schmidt K, Schiemann J	Monitoring the commercial cultivation of Bt maize in Europe--conclusions and recommendations for future monitoring practice	Environmental Biosafety Research	2009	YES	YES	YES	YES
Williams WP, Windham GL, Krakowsky MD, Scully BT, Xinzhi N	Aflatoxin accumulation in BT and non-BT maize Testcrosses	Journal of crop improvement	2010	NO	-	-	-
Wu G, Wu Y, Xiao L, Lu C	Event-specific qualitative and quantitative PCR detection of genetically modified rapeseed Topas 19/2	Food Chemistry	2009	NO	-	-	-
Wu G, Wu Y, Xiao L, Lu C	Event-specific qualitative and quantitative PCR methods for the detection of genetically modified rapeseed Oxy-235	Transgenic Research	2008	NO	-	-	-

⁵⁹ GM plant market registration application with reference EFSA-GMO-RX-Bt11/Application/Part I Technical Dossier/References/2- Environmental aspects

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Wu H, Sun H, Li B, Yang C, Lu X	Detection of genetically modified maize by multiplex PCR-gene chip	Journal of Agricultural Biotechnology	2009	NO	-	-	-
Wu X, Leonard BR, Zhu YC, Abel CA, Head GP, Huang F	Susceptibility of Cry1Ab-resistant and -susceptible sugarcane borer (Lepidoptera: Crambidae) to four <i>Bacillus thuringiensis</i> toxins	Journal of Invertebrate Pathology	2009	NO	-	-	-
Wu XY, Huang FN, Leonard BR, Ghimire M	Growth and development of <i>Bacillus thuringiensis</i> Cry1Ab-susceptible and Cry1Ab-resistant sugarcane borer on diet and conventional maize plants	Entomologia Experimentalis et Applicata	2009	YES	YES	YES	YES
Wu XY, Huang FN, Leonard BR, Moore SH	Evaluation of transgenic <i>Bacillus thuringiensis</i> corn hybrids against Cry1Ab-susceptible and -resistant sugarcane borer (Lepidoptera: Crambidae)	Journal of Economic Entomology	2007	YES	YES	YES	YES
Wu Y, Wang Z, He K, Bai S, Zhao C	Effect of transgenic Bt corn (event Bt11) pollen expressing Cry1Ab toxin on longevity and fecundity of <i>Trichogramma ostriniae</i> (Hymenoptera: Trichogrammatidae) in the laboratory	Acta Entomologica Sinica	2008	YES	YES	NO	-
Xiaodan X, Yingcong L, Heng Z, Si-Yuan W, Sheng-Qi W, Jian H, Kun-Lun H, Yun-Bo L	Rapid and reliable detection and identification of GM events using multiplex PCR coupled with oligonucleotide microarray	Journal of Agricultural and Food Chemistry	2005	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Xing ZJ, Wang ZY, He KL, Bai SX	Degradation dynamics of Cry1Ab insecticidal protein within transgenic <i>Bacillus thuringiensis</i> corn root debris and rhizosphere soil in field	Scientia Agricultura Sinica	2010	YES	YES	NO	-
Xu J, Zhu S, Miao H, Huang W, Qiu M, Huang Y, Fu X, Li Y	Event-specific detection of seven genetically modified soybean and maizes using multiplex-PCR coupled with oligonucleotide microarray	Journal of agricultural and food chemistry	2007	NO	-	-	-
Xu L, Wang Z, Zhang J, He K, Ferry N, Gatehouse AMR	Cross-resistance of Cry1Ab-selected Asian corn borer to other Cry toxins	Journal of Applied Entomology	2010	YES	YES	YES	YES
Xu W, Cao S, He X, Luo YB, Guo X, Yuan Y, Huang K	Safety assessment of Cry1Ab/Ac fusion protein	Food and chemical Toxicology	2009	NO	-	-	-
Xu W, Huang K, Zhao H, Luo Y	Application of immunoaffinity column as cleanup tool for an enzyme linked immunosorbent assay of phosphinothricin- N-acetyltransferase detection in genetically modified maize and rape	Journal of Agricultural and Food Chemistry	2005	NO	-	-	-
Xu W, Yuan Y, Luo Y, Bai W, Zhang C, Huang K	Event-specific detection of stacked genetically modified maize Bt11xGA21 by UP-M-PCR and real-time PCR	Journal of Agricultural And Food Chemistry	2009	NO	-	-	-
Xu X, Li Y, Zhao H, Wen SY, Wang SQ, Huang J, Huang KL, Luo YB	Rapid and reliable detection and identification of GM events using multiplex PCR coupled with oligonucleotide microarray	Journal of Agricultural and Food Chemistry	2005	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Xu Y, Wang ZY, He KL, Bai SX	Histopathological changes in the midgut of larvae of the Asian corn borer <i>Ostrinia furnacalis</i> (Lepidoptera: Crambidae) fed on Bt-transgenic corn expressing Cry1Ab protein	Acta Entomologica Sinica	2009	YES	YES	NO	-
Xu Y, Wang ZY, He KL, Bai SX	Tissue distribution and content of Cry1Ab insecticidal protein in the <i>Bacillus thuringiensis</i> resistant and susceptible Asian corn borer larvae fed on Bt-transgenic corn	Acta Entomologica Sinica	2007	YES	YES	NO	-
Xu Y, Wang ZY, He KL, Bai SX	Effects of transgenic Bt corn expressing Cry1Ab toxin on activities of some enzymes in larvae of the Asian corn borer <i>Ostrinia furnacalis</i> (Guenee) (Lepidoptera: Pyralidae)	Acta Entomologica Sinica	2006	YES	YES	NO	-
Yang L, Guo J, Pan A, Zhang H, Zhang K, Wang Z, Zhang D	Event-specific quantitative detection of nine genetically modified maizes using one novel standard reference molecule	Journal of Agricultural and Food Chemistry	2007	NO	-	-	-
Yang R, Xu W, Luo Y, Guo F, Lu Y, Huang K	Event-specific qualitative and quantitative PCR detection of roundup ready event GT73 based on the 3'-integration junction	Plant Cell Reports	2007	NO	-	-	-
Yanni SF, Whalen JK, Ma BL	Crop residue chemistry decomposition rates and CO ₂ evolution in Bt and non-Bt corn agroecosystems in North America: a review	Nutrient cycling in agroecosystems	2010	YES	YES	YES	YES

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Yoke-Kqueen C, Yee-Tyan C, Siew-Ping K, Son R	Development of multiplex-PCR for genetically modified organism (GMO) detection targeting EPSPS and Cry1Ab genes in soy and maize samples.	International Food Research Journal	2011	NO	-	-	-
Yu HL, Li YH, Wu KM	Risk assessment and ecological effects of transgenic <i>Bacillus thuringiensis</i> crops on non-target organisms	Journal of integrative Plant Biology	2011	YES	YES	YES	YES
Yuan Y, Ke X, Chen F, Krogh PH, Ge F	Decrease in catalase activity of <i>Folsomia candida</i> fed a Bt rice diet	Environmental pollution	2011	NO	-	-	-
Yue B, Huang F, Leonard BR, Moore S, Parker R, Andow DA, Cook D, Emfinger K, Lee DR	Verifying an F(1) screen for identification and quantification of rare <i>Bacillus thuringiensis</i> resistance alleles in field populations of the sugarcane borer <i>Diatraea saccharalis</i>	Entomologia Experimentalis et Applicata	2008	YES	YES	YES	YES ⁶⁰
Zeilinger AR, Andow DA, Zwahlen C, Stotzky G	Earthworm populations in a northern US Cornbelt soil are not affected by long-term cultivation of Bt maize expressing Cry1Ab and Cry3Bb1 proteins	Soil Biology & Biochemistry	2010	YES	YES	YES	YES
Zemek R, Vavrova Z	Assessing the effects of Bt-maize pollen on <i>Typhlodromus pyri</i> (Acari: Phytoseiidae)	IOBC/WPRS Bulletin	2008	YES	NO	-	-
Zhai Z, Xu W, Zhang N, Yan X, Wang Y, Luo Y, Huang K	Event-specific transgenic detection of genetically modified maize LY038	Journal of Agricultural Biotechnology	2011	NO	-	-	-

⁶⁰ Yue et al. (2008) referred to in EFSA (2010b)

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Zhang C, Xu W, Zhai Z, Luo Y, Yan X, Zhang N, Huang K	Universal Primer-Multiplex-Polymerase Chain Reaction (UP-M-PCR) and capillary electrophoresis-laser-induced fluorescence analysis for the simultaneous detection of six genetically modified maize lines	Journal of Agricultural and Food Chemistry	2011	NO	-	-	-
Zhang W, Shi F	Do genetically modified crops affect animal reproduction? A review of the ongoing debate	Animal	2011	NO	-	-	-
Zhang Y, Lai C, Su R, Zhang M, Xiong Y, Qing H, Deng Y	Quantification of Cry1Ab in genetically modified maize leaves by liquid chromatography multiple reaction monitoring tandem mass spectrometry using O-18 stable isotope dilution	Analyst	2012	NO	-	-	-
Zhang YJ, Sun Y, Yuan HB, Wu KM, Peng YF, Guo YY	Effects of transgenic Bt-cry1Ab corn pollen on the growth and development and the activity of three metabolic enzymes in <i>Harmonia axyridis</i> (Pallas) (Coleoptera: Coccinellidae)	Acta Entomologica Sinica	2005	YES	YES	NO	-
Zhang YY, Xu YF, Hussain K, Liu YZ, Lin F	Establishment of a multiplex-PCR system for identification of genetically modified maize events	Middle East Journal of Scientific Research	2010	NO	-	-	-
Zhu X, Chen L, Shen P, Jia J, Zhang D, Yang L	High sensitive detection of cry1ab protein using a quantum dot-based fluorescence-linked immunosorbent assay	Journal of Agricultural and Food Chemistry	2011	NO	-	-	-

Authors of publication	Title of publication	Journal	Publication year	Out of scope	Peer-reviewed publication	Publication in English	Previously discussed and/or cited
Zhu YY, Tian X, Zhao DG	Construction and application of the vector containing the Bar::gus fusion gene and LoxP/FRT recognition site	Genomics and Applied Biology	2011	NO	-	-	-
Zu E, Sun Y, Zhang P	The analysis of natural and synthetic ruby by raman spectra	Spectroscopy and spectral analysis	2010	NO	-	-	-
Zurbrugg C, Hoenemann L, Meissle M, Romeis J, Nentwig W	Decomposition dynamics and structural plant components of genetically modified Bt maize leaves do not differ from leaves of conventional hybrids	Transgenic Research	2010	YES	YES	YES	YES
Zurbrugg C, Nentwig W	Ingestion and excretion of two transgenic Bt corn varieties by slugs	Transgenic Research	2009	YES	YES	YES	YES
Zwahlen C, Andow DA	Field evidence for the exposure of ground beetles to Cry1Ab from transgenic corn	Environmental Biosafety Research	2005	YES	YES	YES	YES
Zwahlen C, Hilbeck A, Nentwig W	Field decomposition of transgenic Bt maize residue and the impact on non-target soil invertebrates	Plant and Soil	2007	YES	YES	YES	YES